issue resulting from the Adoption and Safe Families Act of 1997 (ASFA) and the unintended consequences it could have on some children, particularly those who have found a loving home at WinShape. Rightfully, ASFA seeks to end the ''foster care drift'' that results when children are abused or neglected by their birth parents by placing these children in loving, adoptive homes. In this regard, ASFA has enjoyed great success. Unfortunately, ASFA's provisions do not adequately address the unique situation found in the families at WinShape Homes.

The problem for places like WinShape has resulted from ASFA's structure which pits family reunification against adoption. Under ASFA, states are required to hold ''permanency'' hearings no later than 12 months after placement in foster care to determine whether parental unification with the child or termination of parental rights should take place. Because WinShape Homes cannot adopt children, children at WinShape Homes may face these ''termination proceedings.'' As a result, a child could potentially be removed from the loving family at WinShape and placed in an entirely new family environment. In addition, while WinShape places a priority on maintaining sibling relationships, such termination proceedings may result in breaking this family bond and separating one sibling from the others through the adoptive process.

Mr. Speaker, as this important work to place children in loving, stable homes continues, I ask that the Members of this House examine these provisions regarding ''termination proceedings'' and permanent living arrangements, such as WinShape Homes, that provide a loving and stable home for so many children. In so doing, the House will only improve on the success of the Adoption and Safe Families Act.

Once again, I thank both Chairman THOMAS and Chairman HERGER for their work to promote safe and stable families for our children. I look forward to working with them, the House Leadership and all of my colleagues in this House to ensure that more American children grow up in loving and stable families.

Mr. PORTMAN. Mr. Speaker, I rise today in support of H.R. 2873, the Safe and Stable Families Amendments of 2001. This legislation will increase funding for important programs that protect our nation's children from abuse and neglect. In addition to increasing funding for existing programs, this bill will also create a new program to provide mentoring services for the children of prisoners, and to provide educational opportunities for youth, aging out of foster care.

I especially appreciate the commitment Congress is showing to these programs because I've witnessed the success of these programs firsthand. My district is fortunate to be home to Beech Acres, a community-based organization that provides highly-tailored services to over 17,000 children and families per year. Jim Mason, the President of Beech Acres, has been a leader in pioneering creative programs for parenting.

At Beech Acres, Jim established an innovative Educational Advocacy Center for children to help provide those who have been abused, are in foster care, or have special challenges with the continuity and support that they need. The funds authorized in this bill will be helpful to Beech Acres.

I'm also pleased that the Infant Safe Haven programs was added as an allowable activity within the Safe and Stable Families program. I know that my colleague from California, Representative HERGER, has been working with Representative MELISSA HART to find a way to address the problem of parents who want to relinquish their new born children, and I appreciate their hard work.

This legislation will help make critical improvements in our nation's child protection services. Too often, these children have been neglected first by their parents, and then by society. With this bill, we are continuing our commitment to give these children the support and attention they deserve. I encourage all my colleagues to support its passage.

Mr. CARDIN. Mr. Speaker, I yield back the balance of my time.

Mr. HERGER. Mr. Speaker, I urge support for H.R. 2873, as amended.

Mr. Speaker, I have no further requests for time, and I yield back the balance of my time.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from California (Mr. HERGER) that the House suspend the rules and pass the bill, H.R. 2873, as amended.

The question was taken; and (two-thirds having voted in favor thereof) the rules were suspended and the bill, as amended, was passed.

A motion to reconsider was laid on the table.

□ 1930

BEST PHARMACEUTICALS FOR CHILDREN ACT

Mr. TAUZIN. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 2887) to amend the Federal Food, Drug, and Cosmetic Act to improve the safety and efficacy of pharmaceuticals for children, as amended.

The Clerk read as follows:

H.R. 2887

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Best Pharmaceuticals for Children Act''.

SEC. 2. PEDIATRIC STUDIES OF ALREADY-MARKETED DRUGS.

(a) IN GENERAL.—Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) is amended—

(1) by striking subsection (b); and

(2) by redesignating subsections (c) through through (k) as subsections (b) through (j), respectively.

(b) CONFORMING AMENDMENTS.—Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) is amended in subsection (b) (as redesignated by subsection (a)(2) of this section)—

(1) by inserting after ''the Secretary'' the following: ''determines that information relating to the use of an approved drug in the pediatric population may produce health benefits in that population and''; and

(2) by striking ''concerning a drug identified in the list described in subsection (b)''.

SEC. 3. RESEARCH FUND FOR THE STUDY OF DRUGS LACKING EXCLUSIVITY.

Part B of title IV of the Public Health Service Act (42 U.S.C. 284 et seq.) is amended—

(1) by redesignating the second section 409C (relating to clinical research) as section 409G;

(2) by redesignating the second section 409D (relating to enhancement awards) as section 409H; and

(3) by adding at the end the following:

''SEC. 409I. PROGRAM FOR PEDIATRIC STUDIES OF DRUGS LACKING EXCLUSIVITY.

''(a) LIST OF DRUGS LACKING EXCLUSIVITY FOR WHICH PEDIATRIC STUDIES ARE NEEDED.—

''(1) IN GENERAL.—Not later than 1 year after the date of enactment of this section, the Secretary, acting through the Director of the National Institutes of Health and in consultation with the Commissioner of Food and Drugs and experts in pediatric research, shall develop, prioritize, and publish an annual list of approved drugs for which—

''(A)(i) there is an approved application under section 505(j) of the Federal Food, Drug, and Cosmetic Act;

''(ii) there is a submitted application that could be approved under the criteria of section 505(j) of the Federal Food, Drug, and Cosmetic Act;

''(iii) there is no patent protection or market exclusivity protection under the Federal Food, Drug, and Cosmetic Act; or

''(iv) there is, under section 505A(c)(4)(C) of the Federal Food, Drug, and Cosmetic Act, a referral for inclusion on such list; and

''(B) additional studies are needed to assess the safety and effectiveness of the use of the drug in the pediatric population.

''(2) CONSIDERATION OF AVAILABLE INFORMATION.—In developing the list under paragraph (1), the Secretary shall consider, for each drug on the list—

''(A) the availability of information concerning the safe and effective use of the drug in the pediatric population;

''(B) whether additional information is needed;

''(C) whether new pediatric studies concerning the drug may produce health benefits in the pediatric population; and

''(D) whether reformulation of the drug is necessary;

''(b) CONTRACTS FOR PEDIATRIC STUDIES.—The Secretary shall award contracts to entities that have the expertise to conduct pediatric clinical trials (including qualified universities, hospitals, laboratories, contract research organizations, federally funded programs such as pediatric pharmacology research units, other public or private institutions, or individuals) to enable the entities to conduct pediatric studies concerning one or more drugs identified in the list described in subsection (a).

''(c) PROCESS FOR CONTRACTS AND LABELING CHANGES.—

''(1) WRITTEN REQUEST TO HOLDERS OF APPROVED APPLICATIONS FOR DRUGS LACKING EXCLUSIVITY.—

''(A) IN GENERAL.—The Commissioner of Food and Drugs, in consultation with the Director of National Institutes of Health, may issue a written request (which shall include a timeframe for negotiations for an agreement) for pediatric studies concerning a drug identified in the list described in subsection (a) to all holders of an approved application for the drug under section 505 of the Federal Food, Drug, and Cosmetic Act. Such a written request shall be made in a manner equivalent to the manner in which a written request is made under subsection (a) or (b) of section 505A of the Federal Food, Drug, and Cosmetic Act, including with respect to information provided on the pediatric studies to be conducted pursuant to the request.

''(B) PUBLICATION OF REQUEST.—If the Commissioner of Food and Drugs does not receive a response to a written request issued under subparagraph (A) within 30 days of the date on which a request was issued, the Secretary, acting through the Director of National Institutes of Health and in consultation with the Commissioner of Food and Drugs, shall publish a request for contract proposals to conduct the pediatric studies described in the written request.

''(C) DISQUALIFICATION.—A holder that receives a first right of refusal shall not be entitled to respond to a request for contract proposals under subparagraph (B).

''(D) GUIDANCE.—Not later than 270 days after the date of enactment of this section, the Commissioner of Food and Drugs shall promulgate guidance to establish the process for the submission of responses to written requests under subparagraph (A).

''(2) CONTRACTS.—A contract under this section may be awarded only if a proposal for the contract is submitted to the Secretary in such form and manner, and containing such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

''(3) REPORTING OF STUDIES.—

''(A) Upon completion of a pediatric study in accordance with a contract awarded under this section, a report concerning the study shall be submitted to the Director of National Institutes of Health and the Commissioner of Food and Drugs. The report shall include all data generated in connection with the study.

''(B) AVAILABILITY OF REPORTS.—Each report submitted under subparagraph (A) shall be considered to be in the public domain, and shall be assigned a docket number by the Commissioner of Food and Drugs. An interested person may submit written comments concerning such pediatric studies to the Commissioner of Food and Drugs, and the written comments shall become part of the docket file with respect to each of the drugs.

''(C) ACTION BY COMMISSIONER.—The Commissioner of Food and Drugs shall take appropriate action in response to the reports submitted under subparagraph (A) in accordance with paragraph (4).

''(4) REQUEST FOR LABELING CHANGES.—During the 180-day period after the date on which a report is submitted under paragraph (3)(A), the Commissioner of Food and Drugs shall—

''(A) review the report and such other data as are available concerning the safe and effective use in the pediatric population of the drug studied; and

''(B) negotiate with the holders of approved applications for the drug studied for any labeling changes that the Commissioner of Food and Drugs determines to be appropriate and requests the holders to make; and

''(C)(i) place in the public docket file a copy of the report and of any requested labeling changes; and

''(ii) publish in the Federal Register a summary of the report and a copy of any requested labeling changes.

''(5) DISPUTE RESOLUTION.—If, not later than the end of the 180-day period specified in paragraph (4), the holder of an approved application for the drug involved does not agree to any labeling change requested by the Commissioner of Food and Drugs under that paragraph—

''(A) the Commissioner of Food and Drugs shall immediately refer the request to the Pediatric Advisory Subcommittee of the Anti-Infective Drugs Advisory Committee; and

''(B) not later than 90 days after receiving the referral, the Subcommittee shall—

''(i) review the available information on the safe and effective use of the drug in the pediatric population, including study reports submitted under this section; and

''(ii) make a recommendation to the Commissioner of Food and Drugs as to appropriate labeling changes, if any.

''(6) FDA DETERMINATION.—Not later than 30 days after receiving a recommendation from the Subcommittee under paragraph (5)(B)(ii) with respect to a drug, the Commissioner of Food and Drugs shall consider the recommendation and, if appropriate, make a request to the holders of approved applications for the drug to make any labeling change that the Commissioner of Food and Drugs determines to be appropriate.

''(7) FAILURE TO AGREE.—If a holder of an approved application for a drug, within 30 days after receiving a request to make a labeling change under paragraph (6), does not agree to make a requested labeling change, the Commissioner may deem the drug to be misbranded under the Federal Food, Drug, and Cosmetic Act.

''(8) RECOMMENDATION FOR FORMULATION CHANGES.—If a pediatric study completed under public contract indicates that a formulation change is necessary and the Secretary agrees, the Secretary shall send a nonbinding letter of recommendation regarding that change to each holder of an approved application.

''(d) CONFIDENTIAL COMMERCIAL INFORMATION; TRADE SECRETS.—Nothing in this section requires or authorizes the use or disclosure of confidential commercial information or trade secrets.

''(e) AUTHORIZATION OF APPROPRIATIONS.—

''(1) IN GENERAL.—For the purpose of carrying out this section, there are authorized to be appropriated $200,000,000 for fiscal year 2002, and such sums as may be necessary for each of the fiscal years 2003 through 2007.

''(2) AVAILABILITY.—Any amount appropriated under paragraph (1) shall remain available to carry out this section until expended.''.

SEC. 4. WRITTEN REQUEST TO HOLDERS OF APPROVED APPLICATIONS FOR DRUGS THAT HAVE MARKET EXCLUSIVITY.

Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) is amended in subsection (c) (as redesignated by section 2(a)(2) of this Act) by adding at the end the following:

''(4) WRITTEN REQUEST TO HOLDERS OF APPROVED APPLICATIONS FOR DRUGS THAT HAVE MARKET EXCLUSIVITY.—

''(A) REQUEST AND RESPONSE.—If the Secretary makes a written request for pediatric studies under subsection (b) to the holder of an application approved under section 505(b)(1), the holder, not later than 180 days after receiving the written request, shall respond to the Secretary as to the intention of the holder to act on the request by—

''(i) indicating when the pediatric studies will be initiated, if the holder agrees to the request; or

''(ii) indicating that the holder does not agree to the request.

''(B) NO AGREEMENT TO REQUEST.—

''(i) REFERRAL.—If the holder does not agree to a written request within the time period specified in subparagraph (A), and if the Secretary determines that there is a continuing need for information relating to the use of the drug in the pediatric population (including neonates as appropriate), the Secretary shall refer the drug to the Foundation for Pediatric Research established under section 499A of the Public Health Service Act (referred to in this paragraph as the 'Foundation') for consideration for the conduct of the pediatric studies described in the written request.

''(ii) PUBLIC NOTICE.—The Secretary shall give public notice of a referral under clause (i), including notice of the name of the drug, the name of the manufacturer, and the indication to be studied.

''(C) LACK OF FUNDS.—If, on referral of a drug under subparagraph (B)(i), the Foundation certifies to the Secretary that the Foundation does not have funds available to conduct the requested studies, the Secretary shall refer the drug for inclusion on the list established under section 409I of the Public Health Service Act for the conduct of the studies.

''(D) CONFIDENTIAL COMMERCIAL INFORMATION; TRADE SECRETS.—Nothing in this paragraph requires or authorizes the use or disclosure of confidential commercial information or trade secrets.

''(E) NO REQUIREMENT TO REFER.—Nothing in this subsection shall be construed to require that every declined written request shall be referred to the Foundation.''.

SEC. 5. TIMELY LABELING CHANGES FOR DRUGS GRANTED EXCLUSIVITY; DRUG FEES.

(a) ELIMINATION OF USER FEE WAIVER FOR PEDIATRIC SUPPLEMENTS.—Section 736(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(a)(1)) is amended—

(1) by striking subparagraph (F); and

(2) by redesignating subparagraph (G) as subparagraph (F).

(b) LABELING CHANGES.—

(1) DEFINITION OF PRIORITY SUPPLEMENT.—Section 201 of the Federal Food Drug, and Cosmetic Act (21 U.S.C. 321) is amended by adding at the end the following:

''(kk) PRIORITY SUPPLEMENT.—The term 'priority supplement' means a drug application referred to in section 101(4) of the Food and Drug Administration Modernization Act of 1997 (111 Stat. 2298).''.

(2) TREATMENT AS PRIORITY SUPPLEMENTS.—Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a), as amended by section 2(a)(2) of this Act, is amended by adding at the end the following:

''(k) LABELING SUPPLEMENTS.—

''(1) PRIORITY STATUS FOR PEDIATRIC SUPPLEMENTS.—Any supplement to an application under section 505 proposing a labeling change pursuant to a report on a pediatric study under this section—

''(A) shall be considered to be a priority supplement; and

''(B) shall be subject to the performance goals established by the Commissioner for priority drugs.

''(2) DISPUTE RESOLUTION.—If the Commissioner determines that an application with respect to which a pediatric study is conducted under this section is approvable and that the only open issue for final action on the application is the reaching of an agreement between the sponsor of the application and the Commissioner on appropriate changes to the labeling for the drug that is the subject of the application—

''(A) not later than 180 days after the date of submission of the application—

''(i) the Commissioner shall request that the sponsor of the application make any labeling change that the Commissioner determines to be appropriate; and

''(ii) if the sponsor of the application does not agree to make a labeling change requested by the Commissioner by that date, the Commissioner shall immediately refer the matter to the Pediatric Advisory Subcommittee of the Anti-Infective Drugs Advisory Committee;

''(B) not later than 90 days after receiving the referral, the Pediatric Advisory Subcommittee of the Anti-Infective Drugs Advisory Committee shall—

''(i) review the pediatric study reports; and

''(ii) make a recommendation to the Commissioner concerning appropriate labeling changes, if any;

''(C) the Commissioner shall consider the recommendations of the Pediatric Advisory Subcommittee of the Anti-Infective Drugs Advisory Committee and, if appropriate, not later than 30 days after receiving the recommendation, make a request to the sponsor of the application to make any labeling change that the Commissioner determines to be appropriate; and

''(D) if the sponsor of the application, within 30 days after receiving a request under subparagraph (C), does not agree to make a labeling change requested by the Commissioner, the Commissioner may deem the drug that is the subject of the application to be misbranded.''.

SEC. 6. OFFICE OF PEDIATRIC THERAPEUTICS.

(a) ESTABLISHMENT.—The Secretary of Health and Human Services shall establish an Office of Pediatric Therapeutics within the Office of the Commissioner of Food and Drugs.

(b) DUTIES.—The Office of Pediatric Therapeutics shall be responsible for oversight and coordination of all activities of the Food and Drug Administration that may have any effect on a pediatric population or the practice of pediatrics or may in any other way involve pediatric issues.

(c) STAFF.—The staff of the Office of Pediatric Therapeutics shall include—

(1) employees of the Department of Health and Human Services who, as of the date of enactment of this Act, exercise responsibilities relating to pediatric therapeutics;

(2) 1 or more additional individuals with expertise concerning ethical issues presented by the conduct of clinical research in the pediatric population; and

(3) 1 or more additional individuals with expertise in pediatrics who shall consult and collaborate with all components of the Food and Drug Administration concerning activities described in subsection (b).

SEC. 7. NEONATES.

Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) is amended in subsection (f) (as redesignated by section 2(a)(2) of this Act) by inserting ''(including neonates in appropriate cases)'' after ''pediatric age groups''.

SEC. 8. SUNSET.

Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) is amended by striking subsection (i) (as redesignated by section 2(a)(2) of this Act) and inserting the following:

''(i) SUNSET.—A drug may not receive any 6-month period under subsection (a) or (b) unless—

''(1) on or before October 1, 2007, the Secretary makes a written request for pediatric studies of the drug;

''(2) on or before October 1, 2007, an approvable application for the drug is submitted under section 505(b)(1); and

''(3) all requirements of this section are met.''.

SEC. 9. DISSEMINATION OF PEDIATRIC INFORMATION.

Section 505A of the Federal Food, Drug, and Cosmetic Act, as amended by section 5(b)(2) of this Act, is amended by adding at the end the following:

''(l) DISSEMINATION OF PEDIATRIC INFORMATION.—

''(1) IN GENERAL.—Not later than 180 days after the date of submission of a report on a pediatric study under this section, the Commissioner shall make available to the public a summary of the medical and clinical pharmacology reviews of pediatric studies conducted for the supplement, including by publication in the Federal Register.

''(2) EFFECT OF SUBSECTION.—Nothing in this subsection alters or amends in any way section 552 of title 5 or section 1905 of title 18, United States Code.''.

SEC. 10. CLARIFICATION OF INTERACTION OF MARKET EXCLUSIVITY UNDER SECTION 505A OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT AND MARKET EXCLUSIVITY AWARDED TO AN APPLICANT FOR APPROVAL OF A DRUG UNDER SECTION 505(j) OF THAT ACT.

Section 505A of the Federal Food, Drug, and Cosmetic Act, as amended by section 9 of this Act, is amended by adding at the end the following:

''(m) CLARIFICATION OF INTERACTION OF MARKET EXCLUSIVITY UNDER THIS SECTION AND MARKET EXCLUSIVITY AWARDED TO AN APPLICANT FOR APPROVAL OF A DRUG UNDER SECTION 505(j).—

''(1) IN GENERAL.—If a 180-day period under section 505(j)(5)(B)(iv) overlaps with a 6-month extension under this section, so that the applicant for approval of a drug under section 505(j) entitled to the 180-day period under that section loses a portion of the 180-day period to which the applicant is entitled for the drug, the 180-day period shall be extended—

''(A) if the 180-day period would, but for this subsection, expire after the 6-month extension, by the number of days of the overlap; or

''(B) if the 180-day period would, but for this subsection, expire during the 6-month extension, by 6 months.

''(2) EFFECT OF SUBSECTION.—Under no circumstances shall application of this section result in an applicant for approval of a drug under section 505(j) being enabled to commercially market the drug to the exclusion of a subsequent applicant for approval of a drug under section 505(j) for more than 180 days.''.

SEC. 11. PROMPT APPROVAL OF GENERIC DRUGS WHEN PEDIATRIC INFORMATION ADDED TO LABELING.

(a) IN GENERAL.—Section 505A of the Federal Food, Drug, and Cosmetic Act, as amended by section 10 of this Act, is amended by adding at the end the following subsection:

''(n) PROMPT APPROVAL OF GENERIC DRUGS WHEN PEDIATRIC INFORMATION ADDED TO LABELING.—

''(1) IN GENERAL.—A drug for which an application has been submitted or approved under section 505(j) and which otherwise meets all other applicable requirements under that section shall be considered eligible for approval and shall not be considered misbranded under section 502 even when its labeling omits a pediatric indication or other aspect of labeling pertaining to pediatric use that is protected by patent or by market exclusivity pursuant to clause (iii) or (iv) of section 505(j)(5)(D).

''(2) LABELING OF GENERIC DRUG.—Notwithstanding the provisions of clause (iii) or (iv) of section 505(j)(5)(D), the Secretary may require that the labeling of a drug approved under section 505(j) that omits pediatric labeling pursuant to paragraph (1) include—

''(A) a statement that the drug is not labeled for the protected pediatric use; and

''(B) any warnings against unsafe pediatric use that the Secretary considers necessary.

''(3) RULE OF CONSTRUCTION.—Paragraphs 1 and 2 of this subsection do not affect—

''(A) the availability or scope of exclusivity under this section;

''(B) the availability or scope of exclusivity under section 505 for pediatric formulations; or

''(C) except as expressly provided in paragraph (1) and (2), the operation of section 505.''.

(b) EFFECTIVE DATE.—The amendments made by subsection (a) take effect on the date of the enactment of this Act, including with respect to applications under section 505(j) of the Federal Food, Drug, and Cosmetic Act that are approved or pending on that date.

SEC. 12. ADVERSE-EVENT REPORTING.

(a) TOLL-FREE NUMBER IN LABELING.—Not later than one year after the date of the enactment of this Act, the Secretary of Health and Human Services shall promulgate a final rule requiring that the labeling of each drug for which an application is approved under section 505 of the Federal Food, Drug, and Cosmetic Act (regardless of the date on which approved) include the toll-free number maintained by the Secretary for the purpose of receiving reports of adverse events regarding drugs. With respect to the final rule:

(1) The rule shall provide for the implementation of such labeling requirement in a manner that the Secretary considers to be most likely to reach the broadest consumer audience.

(2) In promulgating the rule, the Secretary shall seek to minimize the cost of the rule on the pharmacy profession.

(3) The rule shall take effect not later than 60 days after the date on which the rule is promulgated.

(b) DRUGS WITH PEDIATRIC MARKET EXCLUSIVITY.—

(1) IN GENERAL.—During the one-year beginning on the date on which a drug receives a period of market exclusivity under 505A of the Federal Food, Drug, and Cosmetic Act, any report of an adverse event regarding the drug that the Secretary of Health and Human Services receives shall be referred to the Office of Pediatric Therapeutics established under section 6 of this Act. In considering the report, the Director of such Office shall provide for the review of the report by the Pediatric Advisory Subcommittee of the Anti-Infective Drugs Advisory Committee, including obtaining any recommendations of such Subcommittee regarding whether the Secretary should take action under the Federal Food, Drug, and Cosmetic Act in response to the report.

(2) RULE OF CONSTRUCTION.—Paragraph (1) may not be construed as restricting the authority of the Secretary of Health and Human Services to continue carrying out the activities described in such paragraph regarding a drug after the one-year period described in such paragraph regarding the drug has expired.

SEC. 13. FOUNDATION FOR PEDIATRIC RESEARCH.

Title IV of the Public Health Service Act (42 U.S.C. 281 et seq.) is amended by adding at the end the following part:

''PART J—FOUNDATION FOR PEDIATRIC RESEARCH

''SEC. 499A. ESTABLISHMENT AND DUTIES OF FOUNDATION.

''(a) IN GENERAL.—The Secretary, acting through the Director of NIH and in consultation with the Commissioner of Food and Drugs, shall establish a nonprofit corporation to be known as the Foundation for Pediatric Research (hereafter in this section referred to as the 'Foundation'). The Foundation shall not be an agency or instrumentality of the United States Government.

''(b) PURPOSE OF FOUNDATION.—The purpose of the Foundation shall be to collect funds and award grants for research on drugs listed by the Secretary pursuant to section 409I(a)(1)(A).

''(c) CERTAIN ACTIVITIES OF FOUNDATION.—

''(1) IN GENERAL.—In carrying out subsection (b), the Foundation may solicit and accept gifts, grants, and other donations, establish accounts, and invest and expend funds in support of a program to encourage donations for the conduct of studies of drugs referred to in subsection (b).

''(2) FEES.—The Foundation may assess fees for the provision of professional, administrative and management services by the Foundation in amounts determined reasonable and appropriate by the Executive Director.

''(3) AUTHORITY OF FOUNDATION.—The Foundation shall be the sole entity responsible for carrying out the activities described in this subsection.

''(d) BOARD OF DIRECTORS.—

''(1) COMPOSITION.—

''(A) The Foundation shall have a Board of Directors (hereafter referred to in this section as the 'Board'), which shall be composed of ex officio and appointed members in accordance with this subsection. Appointed members of the Board shall be the voting members.

''(B) The ex officio members of the Board shall be—

''(i) the Chairman and ranking minority member of the Subcommittee on Health (Committee on Energy and Commerce) or their designees, in the case of the House of Representatives;

''(ii) the Chairman and ranking minority member of the Committee on Health, Education, Labor and Pensions or their designees, in the case of the Senate;

''(iii) the Director of NIH; and

''(iv) the Commissioner of Food and Drugs.

''(C) The ex officio members of the Board under subparagraph (B) shall appoint to the Board 11 individuals from among a list of candidates to be provided by the National Academy of Science. Of such appointed members—

''(i) 5 shall be representative of the experts in pediatric medicine and research field;

''(ii) 1 shall be a biomedical ethicist; and

''(iii) 5 shall be representatives of the general public, which may include representatives of affected industries.

''(D)(i) Not later than 30 days after the date of the enactment of the Best Pharmaceuticals for Children Act, the Director of NIH shall convene a meeting of the ex officio members of the Board to—

''(I) incorporate the Foundation and establish the general policies of the Foundation for carrying out the purposes of subsection (b), including the establishment of the bylaws of the Foundation; and

''(II) appoint the members of the Board in accordance with subparagraph (C).

''(ii) Upon the appointment of the members of the Board under clause (i)(II), the terms of service of the ex officio members of the Board as members of the Board shall terminate.

''(E) The agreement of not less than three-fifths of the members of the ex officio members of the Board shall be required for the appointment of each member to the initial Board.

''(F) No employee of the National Institutes of Health shall be appointed as a member of the Board.

''(2) CHAIR.—

''(A) The ex officio members of the Board under paragraph (1)(B) shall designate an individual to serve as the initial Chair of the Board.

''(B) Upon the termination of the term of service of the initial Chair of the Board, the appointed members of the Board shall elect a member of the Board to serve as the Chair of the Board.

''(3) TERMS AND VACANCIES.—

''(A) The term of office of each member of the Board appointed under paragraph (1)(C) shall be 5 years, except that the terms of offices for the initial appointed members of the Board shall expire as determined by the ex officio members and the Chair.

''(B) Any vacancy in the membership of the Board shall be filled in the manner in which the original position was made and shall not affect the power of the remaining members to execute the duties of the Board.

''(C) If a member of the Board does not serve the full term applicable under subparagraph (A), the individual appointed to fill the resulting vacancy shall be appointed for the remainder of the term of the predecessor of the individual.

''(D) A member of the Board may continue to serve after the expiration of the term of the member until a successor is appointed.

''(4) COMPENSATION.—Members of the Board may not receive compensation for service on the Board. Such members may be reimbursed for travel, subsistence, and other necessary expenses incurred in carrying out the duties of the Board, as set forth in the bylaws issued by the Board.

''(5) MEETINGS AND QUORUM.—A majority of the members of the Board shall constitute a quorum for purposes of conducting the business of the Board.

''(6) CERTAIN BYLAWS.—

''(A) In establishing bylaws under this subsection, the Board shall ensure that the following are provided for:

''(i) Policies for the selection of the officers, employees, and agents of the Foundation.

''(ii) Policies, including ethical standards, for the acceptance, solicitation, and disposition of donations and grants to the Foundation and for the disposition of the assets of the Foundation. Policies with respect to ethical standards shall ensure that officers, employees and agents of the Foundation (including members of the Board) avoid encumbrances that would result in a conflict of interest, including a financial conflict of interest or a divided allegiance. Such policies shall include requirements for the provision of information concerning any ownership or controlling interest in entities related to the activities of the Foundation by such officers, employees and agents and their spouses and relatives.

''(iii) Policies for the conduct of the general operations of the Foundation.

''(B) In establishing bylaws under this subsection, the Board shall ensure that such bylaws (and activities carried out under the bylaws) do not—

''(i) reflect unfavorably upon the ability of the Foundation to carry out its responsibilities or official duties in a fair and objective manner; or

''(ii) compromise, or appear to compromise, the integrity of any governmental agency or program, or any officer or employee involved in such program.

''(e) INCORPORATION.—The initial members of the Board shall serve as incorporators and shall take whatever actions necessary to incorporate the Foundation.

''(f) NONPROFIT STATUS.—The Foundation shall be considered to be a corporation under section 501(c) of the Internal Revenue Code of 1986, and shall be subject to the provisions of such section.

''(g) EXECUTIVE DIRECTOR.—

''(1) IN GENERAL.—The Foundation shall have an Executive Director who shall be appointed by the Board and shall serve at the pleasure of the Board. The Executive Director shall be responsible for the day-to-day operations of the Foundation and shall have such specific duties and responsibilities as the Board shall prescribe.

''(2) COMPENSATION.—The rate of compensation of the Executive Director shall be fixed by the Board.

''(h) POWERS.—In carrying out subsection (b), the Foundation shall operate under the direction of its Board, and may—

''(1) adopt, alter, and use a corporate seal, which shall be judicially noticed;

''(2) provide for 1 or more officers, employees, and agents, as may be necessary, define their duties, and require surety bonds or make other provisions against losses occasioned by acts of such persons;

''(3) hire, promote, compensate, and discharge officers and employees of the Foundation, and define the duties of the officers and employees;

''(4) with the consent of any executive department or independent agency, use the information, services, staff, and facilities of such in carrying out this section;

''(5) sue and be sued in its corporate name, and complain and defend in courts of competent jurisdiction;

''(6) modify or consent to the modification of any contract or agreement to which it is a party or in which it has an interest under this part;

''(7) establish a process for the selection of candidates for positions under subsection (c);

''(8) solicit, accept, hold, administer, invest, and spend any gift, devise, or bequest of real or personal property made to the Foundation;

''(9) enter into such other contracts, leases, cooperative agreements, and other transactions as the Executive Director considers appropriate to conduct the activities of the Foundation; and

''(10) exercise other powers as set forth in this section, and such other incidental powers as are necessary to carry out its powers, duties, and functions in accordance with this part.

''(i) ADMINISTRATIVE CONTROL.—No participant in the program established under this part shall exercise any administrative control over any Federal employee, nor shall the Foundation attempt to influence an executive branch agency or employee.

''(j) GENERAL PROVISIONS.—

''(1) FOUNDATION INTEGRITY.—The members of the Board shall be accountable for the integrity of the operations of the Foundation and shall ensure such integrity through the development and enforcement of criteria and procedures relating to standards of conduct (including those developed under subsection (d)(6)(A)(ii), financial disclosure statements, conflict of interest rules, recusal and waiver rules, audits and other matter determined appropriate by the Board.

''(2) FINANCIAL CONFLICTS OF INTEREST.—Any individual who is an officer, employee, or member of the Board of the Foundation may not (in accordance with policies and requirements developed under subsection (d)(6)(A)(ii) personally or substantially participate in the consideration or determination by the Foundation of any matter that would directly or predictably affect any financial interest of the individual or a relative (as such term is defined in section 109(16) of the Ethics in Government Act of 1978) of the individual, of any business organization or other entity, or of which the individual is an officer or employee, or is negotiating for employment, or in which the individual has any other financial interest.

''(3) AUDITS; AVAILABILITY OF RECORDS.—The Foundation shall—

''(A) provide for annual audits of the financial condition of the Foundation; and

''(B) make such audits, and all other records, documents, and other papers of the Foundation, available to the Secretary and the Comptroller General of the United States for examination or audit.

''(4) REPORTS.—

''(A) Not later than 5 months following the end of each fiscal year, the Foundation shall publish a report describing the activities of the Foundation during the preceding fiscal year. Each such report shall include for the fiscal year involved a comprehensive statement of the operations, activities, financial condition, and accomplishments of the Foundation.

''(B) With respect to the financial condition of the Foundation, each report under subparagraph (A) shall include the source, and a description of, all gifts or grants to the Foundation of real or personal property, and the source and amount of all gifts or grants to the Foundation of money. Each such report shall include a specification of any restrictions on the purposes for which gifts or grants to the Foundation may be used.

''(C) The Foundation shall make copies of each report submitted under subparagraph (A) available for public inspection, and shall upon request provide a copy of the report to any individual for a charge not exceeding the cost of providing the copy.

''(D) The Board shall annually hold a public meeting to summarize the activities of the Foundation and distribute written reports concerning such activities and the scientific results derived from such activities.

''(5) SERVICE OF FEDERAL EMPLOYEES.—Federal employees may serve on committees advisory to the Foundation and otherwise cooperate with and assist the Foundation in carrying out its function, so long as the employees do not direct or control Foundation activities.

''(6) RELATIONSHIP WITH EXISTING ENTITIES.—The Foundation may, pursuant to appropriate agreements, acquire the resources of existing nonprofit private corporations with missions similar to the purposes of the Foundation.

''(7) INTELLECTUAL PROPERTY RIGHTS.—The Board may adopt written standards with respect to the ownership of any intellectual property rights derived from the collaborative efforts of the Foundation prior to the commencement of such efforts.

''(8) NATIONAL INSTITUTES OF HEALTH AMENDMENTS OF 1990.—The activities conducted in support of the National Institutes of Health Amendments of 1990 (Public Law 101–613), and the amendments made by such Act, shall not be nullified by the enactment of this section.

''(9) LIMITATION OF ACTIVITIES.—The Foundation shall exist solely as an entity to collect funds and award grants for research on drugs listed by the Secretary pursuant to section 409I(a)(1)(A).

''(10) TRANSFER OF FUNDS.—The Foundation may transfer funds to the National Institutes of Health. Any funds transferred under this paragraph shall be subject to all Federal limitations relating to federally-funded research.

''(k) DUTIES OF THE DIRECTOR.—

''(1) APPLICABILITY OF CERTAIN STANDARDS TO NON-FEDERAL EMPLOYEES.—In the case of any individual who is not an employee of the Federal Government and who serves in association with the National Institutes of Health, with respect to financial assistance received from the Foundation, the Foundation may not provide the assistance of, or otherwise permit the work at the National Institutes of Health to begin until a memorandum of understanding between the individual and the Director of NIH, or the designee of such Director, has been executed specifying that the individual shall be subject to

such ethical and procedural standards of conduct relating to duties performed at the National Institutes of Health, as the Director of NIH determines is appropriate.

''(2) SUPPORT SERVICES.—The Director of NIH shall provide facilities, utilities and support services to the Foundation.

''(l) REPORTS OF STUDIES; LABELING CHANGES.—

''(1) IN GENERAL.—Upon completion of a pediatric study conducted pursuant to this section, a report concerning the study shall be submitted to the Director of National Institutes of Health and the Commissioner of Food and Drugs. The report shall include all data generated in connection with the study.

''(2) AVAILABILITY OF REPORTS; ACTION BY FOOD AND DRUG ADMINISTRATION; LABELING CHANGES.—With respect to a report submitted under paragraph (1), the provisions of paragraphs (3)(B) through (8) of section 409I(c) apply to such report to the same extent and in the same manner as such provision apply to a report submitted under section 409I(c)(3)(A).

''(m) FUNDING.—

''(1) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this part, there are authorized to be appropriated such sums as may be necessary for fiscal year 2002 and each subsequent fiscal year.

''(2) LIMITATION REGARDING OTHER FUNDS.—Amounts appropriated under any provision of law other than paragraph (1) may not be expended to establish or operate the Foundation.''.

SEC. 14. STUDY CONCERNING RESEARCH INVOLVING CHILDREN.

(a) CONTRACT WITH INSTITUTE OF MEDICINE.—The Secretary of Health and Human Services shall enter into a contract with the Institute of Medicine for—

(1) the conduct, in accordance with subsection (b), of a review of—

(A) Federal regulations in effect on the date of the enactment of this Act relating to research involving children;

(B) federally-prepared or supported reports relating to research involving children; and

(C) federally-supported evidence-based research involving children; and

(2) the submission to the appropriate committees of Congress, by not later than 2 years after the date of enactment of this Act, of a report concerning the review conducted under paragraph (1) that includes recommendations on best practices relating to research involving children.

(b) AREAS OF REVIEW.—In conducting the review under subsection (a)(1), the Institute of Medicine shall consider the following:

(1) The written and oral process of obtaining and defining ''assent'', ''permission'' and ''informed consent'' with respect to child clinical research participants and the parents, guardians, and the individuals who may serve as the legally authorized representatives of such children (as defined in subpart A of part 46 of title 45, Code of Federal Regulations).

(2) The expectations and comprehension of child research participants and the parents, guardians, or legally authorized representatives of such children, for the direct benefits and risks of the child's research involvement, particularly in terms of research versus therapeutic treatment.

(3) The definition of ''minimal risk'' with respect to a healthy child or a child with an illness.

(4) The appropriateness of the regulations applicable to children of differing ages and maturity levels, including regulations relating to legal status.

(5) Whether payment (financial or otherwise) may be provided to a child or his or her parent, guardian, or legally authorized representative for the participation of the child in research, and if so, the amount and type of payment that may be made.

(6) Compliance with the regulations referred to in subsection (a)(1)(A), the monitoring of such compliance (including the role of institutional review boards), and the enforcement actions taken for violations of such regulations.

(7) The unique roles and responsibilities of institutional review boards in reviewing research involving children, including composition of membership on institutional review boards.

(c) REQUIREMENTS OF EXPERTISE.—The Institute of Medicine shall conduct the review under subsection (a)(1) and make recommendations under subsection (a)(2) in conjunction with experts in pediatric medicine, pediatric research, and the ethical conduct of research involving children.

SEC. 15. STUDY ON EFFECTS OF THIS ACT.

Not later than October 1, 2006, the Comptroller General of the United States shall submit to the Congress and the Secretary of Health and Human Services a report that describes the following:

(1) The effectiveness of the amendments made by this Act in ensuring that all drugs used by children are tested and properly labeled, including—

(A) the number and importance for children of drugs that are being tested as a result of such amendments, and the importance for children, health care providers, parents, and others of labeling changes made as a result of such testing;

(B) the number and importance for children of drugs that are not being tested for their use notwithstanding the amendments, and possible reason for this; and

(C) the number of drugs for which pediatric testing has been done, for which a period of market exclusivity has been granted, and for which labeling changes required the use of the dispute resolution process established pursuant to the amendments, together with a description of the outcomes of such process, including a description of the disputes and the recommendations of the advisory committee.

(2) The economic impact of the amendments made by this Act, including an estimate of—

(A) costs to taxpayers in the form of higher expenditures by Medicaid and other government programs;

(B) costs to consumers as a result of any delay in the availability of lower cost generic equivalents of drugs tested and granted exclusivity pursuant to such amendments, and loss of revenue by the generic drug industry and any other affected industry as a result of any such delay; and

(C) benefits to the government, to private insurers, and to consumers resulting from decreased health care costs, including—

(i) decreased hospitalizations, due to more appropriate and more effective use of medications in children as a result of testing and re-labeling because of such amendments;

(ii) direct and indirect benefits associated with fewer physician visits not related to hospitalization;

(iii) benefits to children from missing less time at school and being less affected by chronic illnesses, thereby allowing a better quality of life;

(iv) benefits to consumers from lower health insurance premiums due to lower treatment costs and hospitalization rates; and

(v) benefits to employers from reduced need for employees to care for family members.

(3) The nature and types of studies in children of drugs granted a period of market exclusivity pursuant to the amendments made by this Act, including a description of the complexity of such studies, the number of study sites necessary to obtain appropriate data, and the numbers of children involved in any clinical studies, and the cost of such studies for each type of study identified.

(4) The increased pediatric research capability, both private and government-funded, associated with the amendments made by this Act.

SEC. 16. MINORITY CHILDREN AND PEDIATRIC EXCLUSIVITY PROGRAM.

(a) PROTOCOLS FOR PEDIATRIC STUDIES.—Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) is amended in subsection (c)(2) (as redesignated by section 2(a)(2) of this Act) by inserting after the first sentence the following: ''In reaching an agreement regarding written protocols, the Secretary shall take into account adequate representation of children of ethnic and racial minorities.''.

(b) STUDY BY GENERAL ACCOUNTING OFFICE.—

(1) IN GENERAL.—The Comptroller General of the United States shall conduct a study for the purpose of determining the following:

(A) The extent to which children of ethnic and racial minorities are adequately represented in studies under section 505A of the Federal Food, Drug, and Cosmetic Act; and to the extent ethnic and racial minorities are not adequately represented, the reasons for such under representation and recommendations to increase such representation.

(B) Whether the Food and Drug Administration has appropriate management systems to monitor the representation of the children of ethnic and racial minorities in such studies.

(C) Whether drugs used to address diseases that disproportionately affect racial and ethnic minorities are being studied for their safety and effectiveness under section 505A of the Federal Food, Drug, and Cosmetic Act.

(2) DATE CERTAIN FOR COMPLETING STUDY.—Not later than January 10, 2003, the Comptroller General shall complete the study required in paragraph (1) and submit to the Congress a report describing the findings of the study.

SEC. 17. TECHNICAL AND CONFORMING AMENDMENTS.

Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) is amended—

(1)(A) by striking ''(j)(4)(D)(ii)'' each place such term appears and inserting ''(j)(5)(D)(ii)''; and

(B) by striking ''(j)(4)(D)'' each place such term appears and inserting ''(j)(5)(D)''; and

(2)(A) in subsection (c) (as redesignated by section 2(a)(2) of this Act), in each of paragraphs (1) through (3), by striking ''subsection (a) or (c)'' and inserting ''subsection (a) or (b)''; and

(B) in subsection (d) (as so redesignated), in the last sentence, by striking ''subsection (a) or (c)'' and inserting ''subsection (a) or (b)''.

The SPEAKER pro tempore (Mr. OTTER). Pursuant to the rule, the gentleman from Louisiana (Mr. TAUZIN) and the gentleman from Ohio (Mr. BROWN) each will control 20 minutes.

The Chair recognizes the gentleman from Louisiana (Mr. TAUZIN).

GENERAL LEAVE

Mr. TAUZIN. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days within which to revise and extend their remarks and insert extraneous material on H.R. 2887, the bill under consideration.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Louisiana?

There was no objection.

Mr. TAUZIN. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, I rise today in strong support of the Greenwood-Eshoo Best Pharmaceuticals for Children Act, and I urge swift passage of this bipartisan bill.

For years, drugs used in children were not tested for children. To address this situation, the gentleman from Pennsylvania (Mr. GREENWOOD) and the gentleman from California (Mr. WAXMAN) worked together in 1997 to provide manufacturers with an incentive to

test these drugs in children. The incentive adopted then was an additional 6 months of exclusivity to be added to existing exclusivity or patent protection for testing drugs at the request of the FDA.

No one denies that this incentive has worked. According to the FDA, the pediatric exclusivity provision has done more to generate clinical studies and useful prescribing information for the pediatric population of our country than any regulatory or legislative process to date. Put another way, this bill, this act, has done more to test drugs for children in America than any other legislative initiative in the history of this Congress.

According to the American Academy of Pediatrics, the incentive has advanced therapeutics for infants, children, and adolescents in ways that were not possible in the several decades prior to the passage of the law.

Every children's group in America supports this reauthorization. Without this reauthorization, the law expires. Every children's group is urging us to adopt this bill and to reauthorize this good law. That is why the Committee on Energy and Commerce reported the bill by a strong 41 to six bipartisan vote.

In fact, at the Committee on Energy and Commerce we have the support of Members, such as the gentleman from Michigan (Mr. STUPAK), the gentleman from Texas (Mr. GREEN), the gentlewoman from Colorado (Ms. DEGETTE), the gentleman from Maryland (Mr. WYNN), the gentleman from New York (Mr. ENGEL), the gentleman from Illinois (Mr. RUSH); and the list goes on.

While some may object to this bill today, this is a matter that was so bipartisan that it has already passed the Senate with unanimous consent.

A handful of Members oppose this reauthorization by saying that pediatric exclusivity has provided a windfall to the industry that has increased costs to consumers. Here are the facts: while some companies have benefited financially for testing their drugs in children, the GAO notes that while there has been some concern that exclusivity may be sought and granted primarily for drugs that generate substantial revenue, most of the drugs studied are not the top sellers.

In fact, 20 of the 37 drugs which have been granted exclusivity for performing these tests in children, at the request of the FDA, 20 of the 37 drugs fall outside the top 200 in terms of drug sale revenue. Further, the FDA estimates that the cost of this provision adds about one-half of one percent to the Nation's pharmaceutical bill; but according to Tufts University, it saves us $7 billion in medical costs because we now know what levels to prescribe drugs for children and what children can take what drugs and which children cannot, depending on the weight and age and many other factors.

Another argument against the bill is that it costs too much. Frankly, I, too, was surprised by the CBO score on this bill. While the CBO estimates that the bill will result in direct savings and revenue increases over the next 5 years, they also estimate that it will result in increased discretionary spending over this period.

The flaw in the CBO score is that they assume that the new public fund for the study of generic drugs will study 165 drugs over the next 5 years. That is simply unrealistic. The American Academy of Pediatrics has told our committee that only 30 to 50 generic drugs will need to be studied under this program, not the 165 that was identified by the CBO; and assuming that the experts in pediatric medicine are correct, rather than CBO, this reduces the score by more than $400 million.

The American Academy of Pediatrics, the Coalition for Children'S Health, the National Association of Children's Hospitals, and the Elizabeth Glaser Pediatric AIDS Foundation are all telling us to please pass the Greenwood-Eshoo legislation now. If the program is not reauthorized this year, it expires. So I urge my colleagues, please pass this legislation.

I commend the gentlewoman from California (Ms. ESHOO) for her diligent work on this and the gentleman from Pennsylvania (Mr. GREENWOOD) for their leadership in getting this legislation to the floor.

Mr. Speaker, I reserve the balance of my time.

Mr. BROWN of Ohio. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, I know of no Member of Congress who opposes testing drugs for use in children. I know of no Member of Congress who believes it is okay that drug safety and efficacy and dosage information is available for adults but not for children.

The question is, how much must Americans pay the drug industry to secure this kind of testing? By keeping lower-priced generics off the market, the 6-month exclusivity provisions cost the Federal Government, employer-sponsored health plans, seniors, all of us, literally billions, billions of dollars in inflated drug prices.

The Federal Government instead could pay the companies two, three, four, even five times the cost of doing these tests. It would still cost less than 6 months of exclusivity, but that would be direct government spending and we cannot have that.

The drug industry and my friends in the majority have made it very clear, if the Nation wants prescription drugs to be tested for use in children, we have to help the drug industry choke off its competition. The most profitable industry in the world has convinced us it deserves another multi-billion dollar windfall for conducting $4 million tests.

I thought committee deliberations on this legislation might produce some legitimate argument, but no such luck. The line of reasoning behind this bill goes something like this: 6-month exclusivity works, they tell us. So would handing the drug industry a blank check and asking them to rob us blind. Does that make it a good idea?

Typically policy-makers weigh both the benefits and the costs when formulating public policy. Why are we only weighing the benefits here?

They tell us pediatric exclusivity is the most successful program in our history when it comes to increasing the number of pediatric tests. It is also the only program attempted that offers any economic incentive for pediatric testing. Attempts in the past relied on subtle persuasion, not any kind of economic incentives.

Third, they tell us the carrot works better than the stick. Yes, but how big does the carrot need to be? Do drug companies need to earn a 600 percent to 1,500 percent return on their investment or they will refuse to make sure that their drugs are safe for kids?

They assert that pediatric exclusivity uses marketplace incentives, it is a free market solution. Pediatric exclusivity is not a free market solution. It does not use marketplace incentives. In free markets, competition and demand drive behavior. Monopolies, as this extends, are anathema to free markets.

They tell us that FDA says pediatric exclusivity represents about only a half of 1 percent of the Nation's pharmaceutical bill. If the added costs of pediatric exclusivity were spread evenly over all drug purchases, then the impact would be minimal.

The lost savings, however, are not spread over every purchase. They are imposed only on the consumers who use Prilosec or Vasotec or one of the drugs eligible for exclusivity.

So a constituent calls one of us and says the price of a prescription suddenly doubled, I would make her feel better by saying that increase represents only one half of 1 percent of all prescription drug prices? I do not think so.

They tell us when we factor in lower children's health care costs, pediatric exclusivity actually saves money. I wonder if the authors of this research actually factored in the higher health care costs that accrue when seniors, who cannot afford the inflated drug prices associated with 6-month exclusivity, when they remain ill, or when children who may remain ill, whose parents cannot afford inflated drug prices.

Why do I oppose this legislation? It is costing my constituents too much. It is costing employer-sponsored health care plans too much. It costs the State and Federal Government too much.

Generic competition, remember, typically cuts a drug's price in half initially; and over time, the price difference grows so that consumers are paying 80 percent, even 90 percent, less for a generic drug that this bill wants to keep off the market. For drugs like

Prilosec, Prozac, and Zocor, exclusivity adds $70 to each prescription, and the manufacturer of these drugs will take home an additional, as committee testimony proved, an additional $500 million to $1.6 billion for drug tests that cost about $4 million each. That is why many of us on this side are opposed to this legislation.

I am opposed to considering this bill as a suspension, not only because this Congress should have the opportunity to consider alternatives, but because the gentleman from Michigan (Mr. STUPAK) should have the opportunity to amend the labeling provisions in this bill. Drug companies are rewarded with more market exclusivity before the labels on the drugs are changed to reflect the pediatric information.

Consumers are paying a huge bill, for which they receive a vague promise that labels will change eventually to reflect new information. That makes no sense.

For the sake of children, for seniors, for every consumer, the gentleman from Michigan (Mr. STUPAK) wants to improve this bill. We should revisit this bill.

I urge a ''no'' vote with the best interests of children, their families, consumers, taxpayers, all of us. That means voting no.

Mr. Speaker, I reserve the balance of my time.

Mr. TAUZIN. Mr. Speaker, I am pleased to yield 4 minutes to the gentlewoman from California (Ms. ESHOO), the co-sponsor of this important legislation.

Ms. ESHOO. Mr. Speaker, I thank the distinguished chairman of our committee for his leadership on this, and I am proud to be the Democratic sponsor with the gentleman from Pennsylvania (Mr. GREENWOOD) of the Best Pharmaceuticals for Children Act.

This legislation extents the pediatric exclusivity provision, which is one of the most successful programs created by Congress to inspire medical therapeutic advances for children. Prior to its enactment, 80 percent of all medications had never been tested for use by children, even though most were widely used by pediatricians to treat them. Many of these drugs carry disclaimers stating that they were not approved for children, and pediatricians were literally cutting pills in half and thirds and in quarters, guessing, and essentially experimenting on children as they used anecdotal information or guesswork to use the medications for them. Obviously, this was not acceptable for our Nation's children.

In 1997, the Congress passed a pediatric exclusivity provision as part of the FDA Modernization Act, which I sponsored with the gentleman from Texas (Mr. BARTON) at the time. This provision has made a dramatic change in the way pediatricians are practicing and administering medicine to children.

Now they have the necessary dosage guidance on drug labels to administer drugs safely to children, but there are many more drugs that can and should be used in the pediatric population. This bill ensures that those drugs will also be studied and that information on safe use will be provided to pediatricians.

Because previous attempts for drug studies for children had actually failed, this provision was given a 4-year life span. It expires in January of 2002. That is why we are here today.

The incentive that was granted to drug companies to study drugs for children was to give them 6 months of additional market exclusivity. Some of my colleagues on my side of the aisle do not think that that is right. Actually, the proof is in the pudding because it has worked.

Since the law has been in place, the FDA has received close to 250 proposed pediatric study requests from pharmaceutical companies and has issued nearly 200 requests to conduct over 400 pediatric studies. If this were a business, we would have to say it was good because this never happened before. Yes, there is a carrot that has been taken a bite out of. I think that some of my colleagues do not think that this is good enough.

By comparison, in the 7 years prior to enactment of this provision, only 11 studies were completed. The FDA has granted market exclusivity extensions for 33 products; 20 of them include new labeling information for pediatrics and parents. So I think that better informed decisions are being made and children are being taken better care of.

During our committee deliberations, a number of proposals by my colleagues, the gentleman from New Jersey (Mr. PALLONE), who is here, and the gentlewoman from Colorado (Ms. DEGETTE) were adopted and are part of the underlying bill.

The bill before us also makes some significant improvements, improvements that we thought needed to be made over what we have learned over the last 4 years by creating an off-patent drug fund within NIH and setting up a public-private foundation to support the research necessary for these important drugs.

The bill also addresses some concerns that were raised by both the FDA and the GAO with regard to labeling. The bill enhances the labeling process and provides the FDA commissioner the authority to misbrand a drug if drug companies actually drag their heels and do not do what we are looking for.

Twenty-eight national children's health advocacy groups support this bill's passage. Among them are the American Academy of Pediatrics, the March of Dimes, and the National Association of Children's Hospitals.

This bill deserves to be passed overwhelmingly by the House of Representatives. We should follow in the other body's footsteps, which passed this, by the way, on a unanimous consent.

So I thank the gentleman from Louisiana (Mr. TAUZIN) and the gentleman from Pennsylvania (Mr. GREENWOOD) for their leadership. It has been a pleasure working with my colleagues.

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Mr. BROWN of Ohio. Mr. Speaker, I yield 4½ minutes to the gentleman from Michigan (Mr. STUPAK) who has worked hard on making this bill fairer for consumers and fairer for children and fairer for consumers of prescription drugs.

Mr. STUPAK. Mr. Speaker, I rise tonight to urge Members to vote against H.R. 2887, the Pediatric Exclusivity Act, as it is on the suspension calendar with controversial provisions.

First approved in 1997, pediatric exclusivity granted the drug companies an extra 6 months extension on their patents if they would provide a study to determine if the drug was beneficial to young people. Upon completion of that study, the FDA grants a pediatric exclusivity to the drug which the drug companies then used as a marketing tool to promote and increase drug sales.

The grant of pediatric exclusivity only takes place upon completion of a study without anyone knowing what the study says about the safety, the effectiveness and dosage requirements for young people. There is no requirement to change the labeling on the drug to reflect the changes needed. There is no label to tell the doctors what is the proper dosage, how to dispense and use the drug safely. Before we grant pediatric exclusivity to a drug and it is then marketed as being FDA approved for pediatric use, we should at least know what is the effect of the drug on young people.

Under the current bill, after the study is completed, exclusivity is granted, but whether the drug helps or hurts young people remains a secret and is not disclosed to doctors, patients, or their families. Physicians, patients, and their families should have a right to know about the drug before they ingest it.

If Members take a look at this chart, Lodine was approved on December 6, 1999; it was 9 months later before we had a label change. What did the label tell the doctors, an approximately two times lower dose than has been recommended for adults. For 9 months they did not know to lower the dosage.

Buspar is another drug that got pediatric exclusivity just for doing a study. Safety and effectiveness were not established in patients. The drug did not even work on young people.

Fluvoxamine, approved on January 3, 2000. On September 28, 2000, they make a label change. What does it say? Girls 8 to 11 years of age may require lower dosage. Why does it take 8 months for a doctor and a family to know?

How about Propofol, granted August 11, 1999? Label change February 23, 2001, 18 months later. Serious bradycardia can result from it. It is not indicated for pediatric ICU sedation, as safety has not been established. Incidence of mortality, twice as great.

Mr. Speaker, we need to know that before this drug is put out on the market and it is marketed by the drug companies as being FDA approved for pediatric use. Why should it take 2 to 18 months, and an average of 9 months? Under the current bill, it can go as much as 11 months.

Pediatric exclusivity, the only time labeling is not required is when we are dealing with pediatric exclusivity. Why should we endanger our children?

I cannot offer an amendment, the amendment I offered in committee, I cannot offer it because we are under the suspension calendar. I am asking Members to reject this bill on the suspension calendar. Let us make it better.

Even the FDA says the goal of pediatric exclusivity is labeling. We need to put the label on so we have the information before the doctor prescribes and before the consumer takes this drug. I cannot understand why the majority would not want doctors, patients, and families to know the effect a drug may have on their children.

What is the proper dosage? What is the effectiveness of the drug? And is the drug safe for our children? Why do we have to wait an average of 9 months to find out after this drug is dispensed to our children whether a drug is safe and did the child receive the proper dosage? We need to know that before children take the drug, not 9 or 11 months after.

Mr. Speaker, defeat this legislation on the suspension calendar so we can offer an amendment to tell the drug companies no pediatric exclusivity until a drug is properly labeled, before our children take that drug. Defeat this bill on suspension. Bring it back to the floor with the Stupak amendment to tie pediatric exclusivity to proper labeling.

Mr. TAUZIN. Mr. Speaker, I yield myself 1 minute to respond to the gentleman from Michigan.

First of all, the gentleman knows that he offered three amendments to the committee, two of which were accepted; and the gentleman voted for the bill in committee.

On the last part, I want to make it clear to the House that current law section 502(n) and 301(z) in the regulations that interpret that law prohibit the marketing of exclusivity until the pediatric indication is on the label. That is the law today. What we do in this bill is go further. We make it a priority review on the pediatric indication, and we put a time certain after which it is misbranding if the pediatric indication is not on the label.

The point I am making is that the problem the gentleman is concerned about is already covered in the law as a violation. A pharmaceutical company is prohibited under the law today to market a drug's exclusivity without the pediatric indication being on the label. That is, under current law, prohibited.

Mr. Speaker, I yield 3 minutes to the gentleman from Florida (Mr. BILIRAKIS).

Mr. BILIRAKIS. Mr. Speaker, I thank the gentleman for yielding me this time.

Mr. STUPAK. Mr. Speaker, will the gentleman yield?

Mr. BILIRAKIS. I yield to the gentleman from Michigan.

Mr. STUPAK. Mr. Speaker, it has been good working with the majority. We cannot agree on this amendment. Even the FDA has asked for this amendment. When they testified before our committee in January, they said the weakness is labeling. ''The goal of pediatric exclusivity should be labeling,'' that is a quote from the FDA.

Section 552 does not work in the real world; that is why we need this amendment.

Mr. BILIRAKIS. Mr. Speaker, I rise in support of the bill. If it is not broken, do not fix it. According to the FDA, ''The pediatric exclusivity provision has been highly effective in generating pediatric studies on many drugs and in providing useful new information and product labeling''; that is a quote from them.

The American Academy of Pediatrics states that they ''cannot overstate how important this legislation has been in advancing children's therapeutics.'' The Greenwood-Eshoo legislation reauthorizes this important program, which has worked, for an additional 6 years. It keeps the present incentive in place and makes important improvements. The legislation ensures that off-patent generic drugs are studied, and tightens the time line for making labeling changes.

We heard from the gentleman from Michigan (Mr. STUPAK) before. He believes that this program does not do enough to ensure that pediatricians get access to labeling information. We have worked diligently to address these concerns. The gentleman from Michigan (Mr. STUPAK) I think would be the first one to agree. For 5 hours today, staff has worked together on the bill. Agreement was reached. The gentleman from Michigan (Mr. STUPAK) was concerned, as we all are, that in fact the providers are made aware of any problems that result or any potential problems that result as a result of the testing.

We agreed that there would be language in the legislation that would require the manufacturer to share a summary of the tests and whatnot with all providers. That was agreed to by the gentleman from Michigan (Mr. STUPAK), or at least by his staff. I will put it that way. As I understand it, there is a change of mind in that regard.

We agree that the providers should know. We have worked very diligently to address that. Our bill does make pediatric, what we call ''priority supplements,'' which will speed up the process for getting new labels. Second, by giving the Secretary authority to deem drugs misbranded, we guarantee label changes will be made. We believe, and children's groups agree, that the changes we make are the right compromises to maintain the incentives and get labels changed.

Mr. Speaker, I would like to acknowledge the hard work of the gentleman from Pennsylvania (Mr. GREENWOOD) and the gentlewoman from California (Ms. ESHOO). Their bill enjoys strong bipartisan support. The companion bill passed the Senate without opposition. This bill favorably passed the Committee on Energy and Commerce by a 41-to-6 vote.

I thank the staff that worked so very long and hard on this legislation, including John Ford and David Nelson with the minority; Eric Olson with the office of the gentlewoman from California (Ms. ESHOO); Brent Del Monte with the majority staff; Alan Eisenberg from the office of the gentleman from Pennsylvania (Mr. GREENWOOD); and finally, Mr. Steve Tilton, of my staff. I ask all Members to support this legislation.

Mr. BROWN of Ohio. Mr. Speaker, I yield 4 minutes to the gentleman from California (Mr. WAXMAN) the original author of the Waxman-Hatch Act, who understands the importance of generic drugs and generic competition.

Mr. WAXMAN. Mr. Speaker, before the Greenwood-Eshoo bill which is now under consideration, there was a law called the Greenwood-Waxman bill. It was passed in 1997. It was an attempt to get the pharmaceutical companies to do studies on the dosage and the reactions of drugs for children.

I supported that bill, as the original cosponsor, but I think it was a mistake because we are overpaying for the work of the pharmaceutical companies to test for children. The cost of exclusivity, which was the price we said we would pay for them to do these tests, has exploded beyond any relation to the cost of a drug company doing the pediatric studies.

In the case of one heartburn drug, exclusivity provided between a 30,000 and a 60,000 percent return on the company's investment. The trial was estimated to have cost between $2 and $4 million. The exclusivity is estimated to be worth more than $1.2 billion. In turn, this windfall contributes to skyrocketing insurance premiums, rapid growth in Medicaid budgets and the soaring out-of-pocket costs for seniors on Medicare.

As with each of the delays the drug companies use to postpone generic competition, each time we extend patents or exclusivity, it costs patients money. If we look at just 25 more drugs that are coming up for exclusivity soon, this law will add at least $11 to $12 billion to the Nation's health care bill. The entire budget of the National Institute of Child Health is less than one-tenth of these windfalls, in fact, less than gained for the heartburn drug alone. This is irresponsible public policy. It is bad for the budget, bad for

helping us secure a Medicare drug benefit, and bad for the American public that pays for these drugs.

But the supporters of the drug say, if we do not pay this highway robbery to the drug companies, the companies will stop doing research on children. That is not true. We do not have to pay that much. In subcommittee and in committee, I offered an amendment to provide generous, but not excessive payments to the drug companies to do pediatric trials. We would have paid them twice the cost of doing the trial, 100 percent return on their investment should be enough for anyone.

Although I offered to accept a friendly amendment that would have made it 200 percent, 300, 400, or 500 percent profit, but not even that was good enough for the pharmaceutical manufacturers.

This debate is about how seriously distorted the pharmaceutical marketplace has become, and no wonder senior citizens and people with disabilities and insurers are screaming about drug costs. I am particularly concerned that this legislation results in a windfall for drug makers without even getting the public health and pediatric benefits that were promised.

If we are getting anything back from drug companies, it is supposed to be new information for parents and pediatricians. But as the gentleman from Michigan (Mr. STUPAK) has pointed out, even drugs that are given exclusivity have not been getting their labels changed. He has an amendment that would link the exclusivity to the actual label change. The label change is important. That is what we are paying for. It is the information about the pediatric trials; and the drug companies are getting their side of the bargain, an extended patent period. But the consumers, especially the pediatricians, are not getting what we are bargaining for, which is the information for them to make the best judgment for children.

□ 2000

I would have hoped that the House would have given a chance to debate and support the Stupak amendment and not put this bill on the suspension calendar. I think on the substance of it, it is a bill that is poorly thought out in light of the experience we have had, and I will oppose the bill. But I would also oppose it because the suspension calendar is not the appropriate place for this legislation where an important amendment like the Stupak amendment should be given a chance to be debated.

Mr. TAUZIN. Mr. Speaker, I am pleased to yield 2 minutes to the gentleman from New York (Mr. TOWNS) for whom all of us share great sympathy and concern tonight as New York again experiences another tragedy.

Mr. TOWNS. Mr. Speaker, how soon we forget.

I would like to remind my colleagues of the practice of pediatric medicine before 1997. We need to remember just how difficult it was for physicians to know the proper dosages of certain medicines for their small patients. Is half of an adult dose enough, too much or too little? Before 1997, many children were denied access to medicines because drugs were not produced in dosable forms that could be used by pediatric patients. It was not very encouraging to be a pediatrician prescribing medicine to children, breaking pills in half, breaking pills into quarters; and it was mostly guesswork.

Let me remind my colleagues of what happened in 1997 that changed the practice of pediatric medicine. Let me remind my colleagues, because it happened right here on this floor. We passed the Better Pharmaceuticals for Children Act, which was enacted into law as part of the Food and Drug Administration Modernization Act. You remember this, I hope. Our colleagues saw the importance of enacting this legislation and providing an incentive for research-based pharmaceutical companies to conduct research on pediatric indications for medicines. The Better Pharmaceuticals for Children Act provided additional market exclusivity as an incentive for pediatric studies on new and existing pharmaceuticals. This act will expire on January 1, 2002, unless we pass this legislation before us today to reauthorize it.

Let us pass it so we can protect our little ones, because the health of our children has been greatly improved as a result of this act. Let us not go away saying that we should continue to do guesswork.

Mr. BROWN of Ohio. Mr. Speaker, I yield 3 minutes to the gentleman from Florida (Mr. DEUTSCH), who believes that Astrazeneca's $4 million investment in Prilosec and $1.4 billion in higher prices to consumers is wrong.

Mr. DEUTSCH. Mr. Speaker, there really is no such thing as a free lunch, and what this legislation does is it gives 6 months of additional exclusivity for these companies.

Again, I think it is interesting, first of all these companies develop these drugs without knowing that they would get the additional 6-month exclusivity, so this was not a factor in any of the research to develop the drugs. None of these drugs are being developed because of it. It really is a gift of this additional 6 months of exclusivity.

When we are talking about these billions of dollars, the $1.4 billion for Prilosec or for Prozac about $900 million or for Pepcid $200 million or for Zestril $300 million or for Claritin $580 million, what are we talking about? We are talking about additional profit for these companies. That is not make-believe profit. That profit, that monopoly profit, is coming from our constituents, from us, out of our society, for monopoly reasons, for no good reasons, because the reality is that these drugs would be developed for an incredibly, it seems almost unreal the numbers, the magnitude of what we are talking about.

The gentleman from California (Mr. WAXMAN) mentioned in the committee that he offered a 100 percent return, 200 percent return, 300 percent return, 400 percent return. It is almost like the Biblical tale when they are saying how many righteous people does it need to save the city. And the reality is it did not matter. It did not matter how many righteous people were needed. It does not matter how much profit could be made, because that is what the majority and the supporters of this bill want to see happen. The drugs would be developed, anyway.

As the ranking Democrat on the subcommittee in the introduction to this debate said, we are all for increasing the availability of prescription drugs for children. In fact, there is nothing about the proposals that we offered in the committee, the substantive proposals, that would make less. In fact, they probably would make more because of the availability of not just doing it for drugs that are blockbusters but for other drugs. But those amendments were rejected in the committee.

I urge my colleagues to defeat this bill on suspension. We have the opportunity on a regular order basis to offer amendments. And also to educate our colleagues as much as we possibly can about this. I think this is one of these issues that the light of day shines very brightly; and as it shines very brightly, I believe that in fact it would lead to a program such as some of the proposals in the committee that would not have the $10 billion of these drugs, the 24 drugs that we are talking about, $10 billion that literally is taken out of the pockets of our constituents and given as additional monopoly profits, total monopoly profits to the drug companies. That is the cost of this bill. For my colleagues or anyone who votes for it, I think that should be your standard. You are paying $10 billion for what the reality is you can pay maybe $40 million for. The scale is that dramatic. There is no reason for us to be doing that.

Defeat the bill. I urge my colleagues to vote ''no.''

ESTIMATED COST TO CONSUMERS OF A SIX-MONTH PEDIATRIC EXCLUSIVITY EXTENSION FOR 24 POPULAR DRUGS

Drug	Manufacture	Status of Exclusivity	2000 Sales	Cost to Consumers	Benefit to Brand-Name Drug Manufacturers
Prilosec	ASTRAZENECA	Received	$4,102,195,000	$676,862,175	$1,435,768,250
Prozac	ELI LILLY	Received	2,567,107,000	423,572,655	898,487,450
Pepcid	MERCK	Received	568,684,000	93,832,860	199,039,400
Daypro	SEARLE	Received	163,783,000	27,024,195	57,324,050
Plendil	ASTRAZENECA	Likely to Receive	169,716,000	28,003,140	59,400,600
Zestril	ASTRAZENECA	Likely to Receive	833,359,000	137,504,235	291,675,650

ESTIMATED COST TO CONSUMERS OF A SIX-MONTH PEDIATRIC EXCLUSIVITY EXTENSION FOR 24 POPULAR DRUGS—Continued

Drug	Manufacture	Status of Exclusivity	2000 Sales	Cost to Consumers	Benefit to Brand-Name Drug Manufacturers
Claritin	SHERING	Received	1,667,347,000	275,112,255	583,571,450
Mevacor	MERCK	Likely to Receive	216,661,000	35,749,065	75,831,350
Monopril	BRISTOL MEYERS SQUIBB	Likely to Receive	233,969,000	38,604,885	81,989,150
Paxil	SMITHLINE BEECHAM	Likely to Receive	1,807,955,000	298,312,575	632,784,250
Viracept	AGOURON	Likely to Receive	315,510,000	52,059,150	110,428,500
Zocor	MERCK	Likely to Receive	2,207,042,000	364,161,930	772,464,700
Zoloft	PFIZER	Likely to Receive	1,890,416,000	311,918,640	661,545,600
Ultram	JOHNSON RW	Received	601,465,000	99,241,725	210,512,750
Celebrex	SEARLE	Likely to Receive	2,015,508,000	332,558,820	705,427,800
Cipro	BAYER	Likely to Receive	1,023,657,000	168,903,405	358,279,950
Flovent	GLAXO WELLCOME	Likely to Receive	647,980,000	106,916,700	226,793,000
Serevent	GLAXO WELLCOME	Likely to Receive	448,923,000	74,072,295	157,123,050
Glucophage	BRISTOL MEYERS SQUIBB	Received	1,629,157,000	268,810,905	570,204,950
Avandia	SMITHLINE BEECHAM	Likely to Receive	617,629,000	101,908,785	216,170,150
Duragesic	ALZA	Likely to Receive	352,934,000	58,234,110	123,526,900
Prevacid	TAP PHARM	Likely to Receive	2,832,602,000	467,379,330	991,410,700
Imitrex	GLAXO WELLCOME	Likely to Receive	747,631,000	123,359,115	261,670,850
Norvasc	PFIZER	Likely to Receive	1,597,091,000	263,520,015	558,981,850
Total-24 Drugs			29,258,321,000	4,827,622,965	10,240,412,350

Mr. TAUZIN. Mr. Speaker, we have heard from the laymen. It is time now to hear from the distinguished gentleman from Georgia (Mr. NORWOOD), to whom I yield 2 minutes.

Mr. NORWOOD. Mr. Speaker, I think that it is perfectly clear to me and perhaps to other Members that there really are people in our body that just do not like the pharmaceutical industry. It is a little baffling to me. I do not impugn their motives, I do not question their motives, I just do not understand it because this is a bill not about profits; but this is a bill about making sure that medications that are produced for adults are then further studied for children. I do not understand exactly why a system that has worked so well and has produced what we wanted it to do should be attacked so tonight.

I have time only to make just one point, but the pharmaceutical industry does not choose which drug is to be studied. Therefore, it does not choose which drug can have 6 months' extension on its patent. Not every drug is eligible for pediatric exclusivity. The decision about whether to issue a written request, that rests with the FDA. That is not based on dollars and cents. It is based on which medication needs to be studied. If there is no written request, there is no opportunity for pediatric exclusivity which means the 6 months' extension on their patent. Hence, and for sure, blockbuster drugs like Rogaine and Viagra will never gain the ability to have pediatric exclusivity.

Lastly, I think just on labeling, I want to point out to you that when you go to the drug store and you get your little plastic vial and it has a label on it, the label on the medication is the doctor's orders. The pediatrician has written to the pharmacist what we want on the label. And to imply that pediatricians in this country simply do not have enough sense to understand that a drug produced for an adult has to be changed for a child is wrong. I give them credit to know that they worry about what they write and what kind of prescription they write, and they carefully put the label through the pharmacies on the drug.

I encourage my colleagues to vote for this and let us go forward and study these drugs for the children of this country that has proven to be reliable, the system that we have been under lately.

Mr. BROWN of Ohio. Mr. Speaker, how much time does each side have?

The SPEAKER pro tempore (Mr. OTTER). Each side has 3 minutes remaining.

Mr. BROWN of Ohio. Mr. Speaker, I yield the balance of my time to the gentleman from New Jersey (Mr. PALLONE), who knows that Eli Lilly's $4 million investment in Prozac and $900 million increase in profits robs consumers.

Mr. PALLONE. Mr. Speaker, I listened to what the gentleman from Georgia (Mr. NORWOOD) said about perhaps some of us who are opposed to this bill not liking the pharmaceutical industry. Let me say that is not true. The pharmaceutical industry is a major industry in my State and particularly in my district. But the point that I think those of us opposed to this bill are trying to make is that there is no reason to continue a Federal program that can provide the same service for much less cost to the consumer at a time when we know that the high cost of prescription drugs is making it difficult for consumers to have access to them.

We all agree in this debate, Mr. Speaker, that we have an enormous responsibility to our children. I have three children, 4, 6, and 8 years old. Above all else, we must ensure that the prescription medications our children may have to take are in fact tested appropriately and deemed safe for children. But the intent of this law was to create an incentive for companies to discover new pediatric uses for their products in exchange for 6 months of exclusivity for the work done.

There are several drawbacks. When the other side says that this program works, I would maintain that it does not work. It certainly does not work as well as it should. According to the HHS report on the pediatric exclusivity provision, the FDA's interpretation of the law has in essence been granting companies patent extensions without receiving the pediatric benefits it was intended to generate. The report states that the incentive has naturally tended to produce pediatric studies on those products where the exclusivity has the greatest value to the product's sponsor. This has left some drugs of importance to children, but for which the incentive has little or no value, unstudied.

Additionally, I am concerned that granting 6 months of exclusivity has a very dramatic financial impact on consumers. This type of a patent extension serves as yet another obstacle that blocks access to generic drugs for consumers, forcing seniors and others to pay higher prices because lower-cost alternatives are needlessly kept off the market. The HHS report states again that the Secretary finds that the impact of the lack of lower-cost generic drugs on some patients, especially those without health insurance and the elderly, may be significant.

Mr. Speaker, I cannot emphasize enough that testing of drugs for pediatric use is essential. Again, I have small children so I understand that. However, I feel that reauthorizing the pediatric exclusivity provision would simply provide tightly budgeted dollars to an industry that can afford to protect children's health with less of an incentive. I said in committee and I will say again on the floor, I do not think the pharmaceutical industry needs an incentive to conduct studies to ensure safety for children. Frankly, I think they should do it as a public service. But as the gentleman from California (Mr. WAXMAN) said, we are not asking them to do it for free. We have stated many times that we would provide twice the cost for profit or 200 percent or 300 percent, whatever. We offered all these amendments in committee. But the bottom line is that they are getting a windfall, and it is too much of a windfall. This was something we tried, but it does not have to be repeated again because it is not helpful to the consumer.

Mr. TAUZIN. Mr. Speaker, I am pleased to yield the balance of my time to close on this important bill, which is supported by every children's health group in America, to the gentleman from Pennsylvania (Mr. GREENWOOD), the author of the legislation and the chairman of the Subcommittee on Oversight and Investigations.

Mr. GREENWOOD. Mr. Speaker, I thank the gentleman for yielding time, and I thank him for his great support in moving this legislation to the floor tonight. It has been a good debate; but I think at the end of the debate it is time to get our focus back on what this bill is about. It is about children. That is why it is called the Best Pharmaceuticals for Children Act.

In the history of medicine in America, we could never figure out a way to get the drug companies to do studies on children, delicate children, children who get sick from taking drugs. We could never find a way to get these studies done so we could bring the benefits of modern medicine that the elderly enjoy, that the middle-aged enjoy, fully to the children of America.

□ 2015

It could not be done. In 1997, my Democratic proponent of this bill, the gentleman from California (Mr. WAXMAN) and I, wrote legislation that did that. We broke the impasse after all of those years, and we have just begun to reap the benefits from it. The children of America have just begun to reap the benefits from it.

The Federal Food and Drug Administration said, ''The pediatric exclusivity provision has done more to generate clinical studies and useful prescribing information for the pediatric population than any other regulatory or legislative process to date,'' period. That practically says it all.

But there are two arguments that have been raised. The gentleman from Michigan (Mr. STUPAK) raises a relatively arcane argument about labeling. This bill is all about labeling. This bill is about making sure that when a doctor sees a sick child and a doctor thinks medicine is good for that child, the doctor can open the box, pull out the pills, read the label and find what is the best dosage for children.

How do we do that? We do that by creating an incentive for these studies to be done. And when the pediatric exclusivity is determined has nothing to do with how the product is marketed. The fact of the matter is, we give them 6 months exclusivity, and in return, we get decades and decades and decades of good knowledge about how to make sick children well.

You can take my word for that, or you can take the word of the gentleman from Michigan (Mr. STUPAK) on that, or you can take the words of the General Accounting Office, which said ''The pediatric exclusivity provision has been successful in encouraging drug sponsors to generate needed information about how drugs worked in children. The infrastructure for conducting pediatric trials has been greatly strengthened.''

Now, there is a second argument. The second argument is this question about are we paying the drug companies too much to do these tests?

The basic premise of the bill is this: If the FDA asks you to study your drug on children and you do the study, you add 6 months to your patent before it expires. It is the same for everyone.

Now, the tortured logic of the opposition is, here is what we should do: If your drug is so successful in reducing suffering in America, so successful in curing the disease, you get penalized; now, if you have a drug that is not so successful, not a lot of people take it, it does not seem to be all that popular with the medical community, well, we will let you make more.

We want to penalize success, and to penalize these companies for easing the pain and the suffering of Americans through the products they make is ridiculous. We ought to all get behind this bill, like every children's health group in America has, and support it overwhelmingly because it deserves that kind of support.

Today, Mr. Speaker, I am happy that the House is considering H.R. 2887, the Best Pharmaceuticals for Children Act.

This bill is the essence of bipartisan policy. It was reported out of the Energy and Commerce Committee by a vote of 41–6, and the Health Subcommittee by a vote of 24–5. Chairman TAUZIN and Chairman BILIRAKIS thank you for your leadership in moving this bill from committee to the floor.

Mr. Speaker, I am also pleased to have worked with Ms. ESHOO and the 16 other members of the minority who have cosponsored this legislation.

H.R. 2887 represents public policy at its best. There are now 197 drugs being studied that are undergoing 400 studies with respect to how these drugs affect kids. Contrast this with the change from the prior 6 years, when only 11 studies had been done.

As the Food and Drug Administration itself said in its report to Congress, the Better Pharmaceuticals for Children Act has had ''unprecedented success,'' and ''the pediatric exclusivity provision had done more to generate clinical studies and useful prescribing information than any other regulatory or legislative process to date.''

This act has helped get drugs to kids who need them, let us better understand how drugs work in kids, and also know when we should and should not be giving kids certain drugs. Or as Linda Suydam, the FDA representative who testified before the Health Subcommittee earlier this year pointed out, ''The results speak for themselves.''

Let me give an example of how this has worked:

Take LODINE, which is prescribed for juvenile rheumatoid arthritis. This drug did not have safety and effectiveness in children established prior to this program. With the studies, we have determined a new indication for children 6–16 years in age and recommended a higher dosage in younger children.

Contrast this with the traditional mindset of just ''taking the pill and breaking it in half'' to determine the dosage for children.

This has been an incredibly effective law. But we can do even better.

Six of the 10 most used drugs by children have not been studied because they are off-patient. This bill will provide the funds for the studies to be completed on those off-patient drugs that are used so often to treat our children. Furthermore, we have developed a foundation to provide resources for the completion of these studies that will have so much value.

Some will argue that this is a Republican bill, helping drug companies. Nothing could be further from the truth. This bill, which I am proud to work on with Ms. ESHOO, is the very essence of bipartisanship. It passed out of the subcommittee by a vote of 24–5. And today, we have more Democrat cosponsors than Republican, including several members of the committee.

Some of my colleagues on the opposite side of the aisle will try to suggest that this bill is both costly and helps blockbuster drugs stay-off competition. This provision is not about blockbuster drugs. Over half of the 38 drugs that have been granted exclusivity do not even make the list of top 200 selling drugs.

Simply put, this bill is good policy. It is sound. It is tested. It is tried. It works.

We need to reauthorize pediatric exclusivity. Vote yes on H.R. 2887.

Mr. DINGELL. Mr. Speaker, I rise to oppose passage of H.R. 2887, a bill that would continue a program that grants drug companies an additional six month period of market exclusivity, if they conduct tests on the use of their drugs for children. Make no mistake; there is complete agreement on the part of all Members that improved testing and labeling of prescription drugs for use in children is a good thing. The only question for debate is how to accomplish that important public health objective.

In 1997, when this law was enacted, the economy was healthier and drugs were cheaper. Even then, I expressed concern about the detrimental impact this provision could have the availability of generic drugs. It is now my view that we made a mistake in enacting the pediatric exclusivity law. First, it establishes a voluntary ''incentive'' for activity that should instead simply be required. Second, assuming that we choose to provide an incentive, the exclusivity program is more expensive, less equitable, and less efficient than any number of alternatives.

Let there be no doubt. The central feature of this bill, exclusivity, is about further increasing the profits of an already bloated industry—an industry that does not seem to be able to moderate its pricing practices even as it increasingly burdens its customers, American consumers, and taxpayers. For example, one drug, Prilosec, earned an additional $1.4 billion during the six months of additional monopoly pricing that AstraZeneca enjoyed. Another drug, Prozac, earned Eli Lilly an additional $900 million.

Indeed, of the 38 drugs that have been granted pediatric exclusivity, less than 20 of them now have pediatric labeling. The companies are not even required to make public the results of the studies they agreed to perform. The Committee rejected, unwisely in my view, an amendment by Representative Stupak that would have closed this dangerous loophole in the law by conditioning the grant of exclusivity to actual pediatric labeling. Don't just take my word for it. The American Academy of Pediatrics, the Food and Drug Administration (FDA), and many supporters of this legislation have declared that the absence of pediatric labeling of drugs used by children presents serious health risks to them.

How much did these studies cost the manufacturers? An average of less than $4 million each. How much did this cost American consumers? For only 24 drugs that either have received or will likely receive pediatric exclusivity under this bill, their sponsors will net $11.5 billion and cost consumers $5.4 billion over the five fiscal years of the program. Depending on future price increases, the total windfall to the brand name pharmaceutical industry could easily exceed $20 billion. The Prilosec windfall alone is worth more to AstraZeneca than the Administration's entire 2002 budget request for the FDA.

The impact of pediatric exclusivity falls directly on those who consume the drugs that get the exclusivity. Who are these people? They include seniors, many that cannot afford the prescription drugs they need. And, ironically, pediatric exclusivity can hurt the very people it is intended to help because many unemployed, uninsured, and working poor cannot afford the expensive drugs needed by their children.

During the Subcommittee and Full Committee mark-ups, Democratic colleagues offered amendments that were collectively aimed at enhancing the protection afforded to children when they take prescription drugs and designing programs that minimize and equitably allocate the financial burden. Unfortunately, we will not be allowed to offer those amendments today. Any of them would have saved consumers billions and offered the same or better benefits in the accurate labeling of these medicines for children. But the Republican Leadership has chosen to hide behind process and avoid votes on these ideas. I urge my colleagues to vote no so we can have the opportunity to craft a more efficient and equitable way to accomplish this important public health objective.

Several potential, and very serious, abuses of the Hatch-Waxman procedures have been uncovered during the course of the discussions with the FDA regarding the technical provisions of this bill. We learned that one company, Bristol Meyers Squibb, had apparently succeeded in convincing FDA that it was entitled to all additional 3½ years of exclusivity for the same pediatric study of its drug, Glucophage, that Bristol Meyers Squibb they had submitted to acquire the initial six months of monopoly marketing. Three of those years of alleged exclusivity were based on the company's claim that a study of some 68 pediatric patients was sufficient to merit a new indication of use claim under Section 505(j) of the Act. Normally, such claims only result in differential labeling between a product that was the subject of a new trial and other therapeutically equivalent products on the market. However, Bristol has apparently succeeded in convincing at least some of the decisionmakers in FDA that the differential labeling regarding pediatric use may constitute a safety risk if not found on equivalent generic products. Because FDA has granted three-year exclusivity to the pediatric label of Glucophage, Bristol has argued that no generic may be marketed during the pendency of its labeling exclusivity.

Most Members recognize this argument as a fundamental abuse of the system and were the FDA and the Bush Administration to accept the claim, consumers would be harmed. I am happy to note that H.R. 2887 closes this potential loophole by instructing the FDA to approve generic drugs without proprietary pediatric labeling awarded to product sponsors under the Hatch-Waxman Act.

However, this is merely a partial fix of the abuses that can arise from decisions of the FDA that performing 505(j) studies for ''new indications'' allows the grant of exclusivity for studies that merely segment the population for which there is an already approved treatment. While differential pediatric labeling may not prevent the development of a competitive market for a drug product, generic labeling or labeling based on race, gender or a host of other distinctions within a population could ''evergreen'' the monopoly enjoyed by a drug manufacturer and the inflated prices charged all consumers.

Not surprisingly, attempts to close this potential three-year loophole were opposed by the brand name industry. We can now expect a rush of petitions to the FDA to approve special labeling for sub-populations that, in many cases, will cost consumers billions of dollars for each drug. Even worse, such studies would divert research dollars into preserving existing monopolies instead of developing new products, the purpose of government protection. This would be quite a legacy for the FDA, for the Bush Administration, and for the House Republican Leadership.

Ms. DEGETTE. Mr. Speaker, I rise today in support of H.R. 2887, the ''Best Pharmaceuticals Act for Children.'' Passage of this bill will continue to enhance our understanding of which medications are safe and efficacious for children by reauthorizing the pediatric exclusivity program.

I thank Chairman TAUZIN and Mr. GREENWOOD for including two of my provisions in this bill. Their inclusion will help to ensure that the program works for all children. These provisions will aid in increasing the representation of ethnic and racial minority children in clinical trials covered under the Act. It certainly has the potential of impacting the families of half my constituents—49.5 percent of who are ethnic or racial minorities.

My provisions require General Accounting Office to conduct a study to examine the extent to which minority children are adequately represented in studies covered by Act. The study will also explore whether drugs used to treat diseases that disproportionately affect ethnic and racial minorities are being studied for their safety and efficacy. This line of inquiry is key as myriad diseases including diabetes, heart disease, sickle cell anemia, and others disproportionately affect ethnic and racial minorities, we must ensure that medications used to treat these ailments are studied.

Additionally, the bill permits the Secretary of Health and Human Services to take into account the presence of adequate representation of ethnic and racial minority children when negotiating written protocols with clinical sponsors. This additional language highlights the need to include this population among study participants.

Mr. Speaker, both additions to the bill help to ensure that all children, white, black, and brown receive the best health care possible. The demographic changes that are anticipated over the next decade magnify the importance of this issue.

While I am in support of this measure, I am concerned that its placement on the suspension calendar precludes Members who have concerns about the bill from bringing their issues and proposed solutions to the House floor for consideration by all Members. I hope their issues are addressed as we work out the differences between the Senate and House passed versions.

Ms. HARMAN. Mr. Speaker, I would like to thank my colleague from California for the opportunity to speak in support of this important legislation.

The Best Pharmaceuticals for Children Act is about harnessing the promise of the most advanced pharmaceuticals for the most vulnerable members of our society. Dr. Jay Lieberman, a pediatric disease specialist from my district, has told me that literally every day he sees children with serious, sometimes life-threatening infections, on whom he must use antibiotics and other drugs that have not been tested to determine how safe they are for children.

''Are we using too much drug?'' he asks. ''Not enough? Will there be adverse effects in children that have not been seen in adults? We can only hope that our sickest infants and children don't die because of our ignorance.''

We must do all we can to end this ignorance, and thanks to the extension of patent exclusivity for companies that test their pharmaceuticals for children, we have already accomplished much. Over the past four years. pharmaceutical companies have dramatically increased the number of pediatric trials for new prescription drugs. More products are being labeled with the proper dosage for children and potentially harmful interactions, and more companies are conducting research into special drug formulations for children.

Today we have the opportunity to act to renew and strengthen the legislation that has made this possible. I urge all my colleagues to vote for the Best Pharmaceuticals for Children Act.

Mr. UPTON. Mr. Speaker, as an original cosponsor of H.R. 2887, The Best Pharmaceuticals for Children Act, I am very pleased that we are taking it up tonight under the Suspension Calendar. As the FDA's report to Congress earlier this year indicated, ''the pediatric exclusivity provision has been highly effective in generating pediatric studies and in providing useful new information on product labels.'' It is important that we reauthorize this very effective program to protect and improve children's health.

The bill before us today makes some important improvements in current law. Under current law, there is little incentive to perform the studies necessary to label off-patent drugs for pediatric use. This bill establishes a federally funded program operated through the NIH and the FDA to contract for studies of off-label drugs. It also establishes a nongovernmental foundation to fund these studies as well as other pediatric research. I have confidence that this foundation's work will be generously supported by the pharmaceutical industry, which indicated in a recent letter to Chairman Tauzin that ''such a charitable foundation is an excellent idea.''

Third, the bill provides the user fees that the FDA has requested to speed up the consideration of applications for labeling changes to reflect pediatric use and gives priority status to the review of these applications.

Fourth, the bill establishes an Office of Pediatric Therapeutics at the FDA to coordinate and oversee pediatric activities across the agency.

Mr. Speaker, I urge all of my colleagues to join me in supporting the Best Pharmaceuticals for Children Act. In the interest of children's health, we cannot allow the pediatric exclusivity provisions to expire at the end of this year.

Ms. JACKSON-LEE of Texas. Mr. Speaker, on October 11, 2001, the Committee on Energy and Commerce favorably reported H.R. 2887, the ''Best Pharmaceuticals for Children Act.'' I commend the Committee for its great work to reauthorize legislation to promote labeling of prescription drugs for use in children. As the Chairwoman of the Congressional Childrens' Caucus, I am concerned that a section

of this legislation may violate the Takings Clause of the United States Constitution. As a member of the Committee on the Judiciary, I have vigorously sought to protect private property rights and to pursue just compensation for those whose property rights are violated. My analysis of section 11 of H.R. 2887, brings me to the conclusion that it would violate current exclusive rights of manufacturers and in turn expose the U.S. government to substantial claims for just compensation. Attached are legal memoranda prepared by the law firm of Wilmer, Cutler & Pickering that validate my concerns:

MEMORAUNDUM TO THE HOUSE ENERGY AND COMMERCE COMMITTEE

Subject: Legal Analysis of the Proposed Amendment to the Hatch-Waxman Act Concerning Approval of Generic Versions of Drugs Without Pediatric Labeling

Congress and the FDA have long sought to encourage pharmaceutical manufacturers to continue researching and refining their products once they are on the market. They have been particularly concerned with developing much-needed clinical research into the efficacy and safety of existing adult drugs for children. To give manufacturers an incentive to engage in research and develop new uses for their products, current law gives manufacturers a three-year exclusive right to market their products with any FDA-approved labeling changes that are based on new clinical research. (Since drugs cannot now be marketed without FDA-approved labeling, this restriction is the equivalent of a three-year exclusive right to market the products themselves.) To provide an extra incentive to conduct clinical research regarding children's health, current law grants manufacturers an additional six-month extension of market exclusivity for any FDA-approved label change based on pediatric clinical trials.

In exchange for this promise of exclusive marketing rights, manufacturers have spent tens of millions of dollars to conduct research into whether their adult products are safe and effective for children and to develop appropriate dosage, indication, and other labeling information for pediatric use. Bristol-Myers Squibb (''BMS''), for example, has spent significant resources on pediatric trials for Glucophage, its type 2 diabetes medicine, and has developed guidelines for the product's safe and effective use for children. BMS did this work at the express request of the FDA, which was concerned that none of the oral type 2 diabetes treatments on the market were approved for pediatric use.

On October 11, however, the House Commerce Committee adopted a proposed amendment to these provisions that would strip away these exclusive marketing rights for existing products like Glucophage. The proposed legislation would likely be found to take pharmaceutical manufacturers' intellectual property within the meaning of the Fifth Amendment, thereby exposing the Treasury to massive claims for just compensation. The proposed legislation also reneges on the express quid pro quo the government has promised manufacturers like BMS, exposing the United States to breach of contract litigation similar to that following the savings and loan crisis. In sum, the proposed legislation presents a certain risk of litigation and a substantial risk of large judgments against the Treasury.

1. THE PROPOSED LEGISLATION WOULD EFFECT A ''TAKING'' OF PRIVATE PROPERTY FOR WHICH ''JUST COMPENSATION'' WOULD LIKELY BE REQUIRED

The Takings Clause of the Fifth Amendment to the United States Constitution provides that the federal government may not take ''private property . . . for public use, without just compensation.'' U.S. Const. amend V. The Supreme Court has concluded that intellectual property—including exclusive rights to use such property—is protected by this Clause, and that when such property is taken for a ''public use,'' compensation to the owner of the property must be made. See Ruckelshaus v. Monsanto Co., 467 U.S. 986, 1001–1004 (1984).

Pharmaceutical manufacturers' current exclusive rights to market their products are no different from patents or other intellectual property and would be protected by the Takings Clause. The proposed legislation may interfere with BMS's (and other manufacturers' rights) in at least two distinct ways. First, under current law, including the pertinent FDA regulations governing the ''misbranding'' of prescription drugs, BMS has the exclusive right to distribute Glucophage for both adult as well as pediatric use. Two separate provisions of the Federal Food Drug and Cosmetic Act (''FEDCA'') provide BMS with the exclusive right to label Glucophage for pediatric use. As a result of this statutory exclusivity, another manufacturer may not distribute Glucophage bearing labeling for pediatric use until June 15, 2004.

But the legal effect of the statutory exclusivity is broader than mere pediatric use. Under the FDA'S ''misbranding'' regulations, manufacturers of prescription drugs must provide labeling information related to pediatric as well as adult use. See 21 C.F.R. §201.57(f)(9). A drug that is ''misbranded'' may not be marketed or distributed, see, e.g., 21 U.S.C. §352(a), and as a result, generic manufacturers are prevented by current law from distributing Glucophage at all. In short, when BMS obtained the exclusive right to pediatric labeling, the legal effect of that exclusive right was to obtain the exclusive right to market Glucophage for adult as well as pediatric use. According to the proposed legislation, however, BMS would lose this exclusive right, because a generic manufacturer of Glucophage would be deemed to be in compliance with the FDA's labeling laws without including the required pediatric use by including on their labels ''a statement that the drug is not labeled for the protected pediatric use'' and ''any warnings against unsafe pediatric use that the Secretary considers necessary.''

Second, the proposed legislation would, as a practical matter, eviscerate the exclusive right to pediatric labeling that BMS obtained under federal law. Once the generic versions are introduced into the market, even though they are not specifically labeled for pediatric use, doctors may nonetheless prescribe those same drugs to children for off-label use. This fairly common practice would eliminate the value of the market exclusivity for pediatric labeling to which BMS is entitled under federal law.

These two incursions onto BMS's rights maybe deemed to constitute a compensable taking of its intellectual property. Courts typically consider several factors when determining whether a governmental action constitutes a taking, including ''the character of the governmental action,'' ''its economic impact,'' and ''its interference with reasonable investment-backed expectations.'' Ruckelshaus, 467 U.S. at 1005. Similar to Ruckelshaus, ''force of [the third factor]''—interference with reasonable, investment-backed expectations—''is so overwhelming . . . that it disposes of the taking question.'' Id. at 1005. BMS obtained the statutory exclusivity only after making substantial investments in clinical studies, doing so in the reasonable expectation that its exclusivity to market Glucophage would be extended for an additional three and one-half years. Even assuming that the BMS did not receive a de jure exclusive right to market Glucophage for all uses, it certainly had the reasonable expectation that its right to exclusive pediatric use would not be later eviscerated by a new labeling regime.

But the other factors also play a key role. The new legislation would have a distinct ''economic impact'' on BMS, by preventing it from enjoying the valuable intellectual property rights that the FFDCA and the pertinent FDA regulations conferred. And unlike traditional forms of economic regulation, ''the character of the governmental action'' would suggest that a taking occurred, because the proposed statute would effectively divest BMS of the intellectual property described above.

Accordingly, the proposed legislation presents a substantial risk that the federal government will be forced to compensate BMS for the loss of its valuable intellectual property. Given the large expected sales of Glucophage, the amount of compensation required could likewise be large.

II. THE PROPOSED LEGISLATION WOULD BREACH THE GOVERNMENT'S IMPLIED CONTRACT WITH MANUFACTURERS SUCH AS BMS.

As the FDA recognized when it authorized BMS to begin clinical trials on Glucophage in children, the absence of information on the use of oral drugs to treat type 2 diabetes in children is a significant public health issue. Type 2 diabetes has become, in recent years, increasingly prevalent in children, recent epidemiological studies indicate that up to forty percent of newly diagnosed diabetic children have type 2 disease. Until last year, however, none of the fourteen oral medications approved for treatment of type 2 diabetes had been approved by the FDA for use in children.

Based on this treatment gap, in 1998 the FDA issued a written request to BMS seeking initiation of clinical studies regarding the safety and effectiveness of Glucophage in children; pursuant to this request, BMS agreed to conduct such studies. By responding favorably to the FDA's request for clinical trials, BMS stood to reap several significant advantages with respect to its exclusivity over Glucophage. Under the exclusivity provisions of the FFDCA, 21 U.S.C. §355a, completion of a pediatric clinical trial in accordance with the FDA's specifications entitles the patent holder to six months' additional exclusivity over the drug. Moreover, under provisions of the Hatch-Waxman Act, 21 U.S.C. §355(j)(5)(D)(iv), and the regulations promulgated thereunder, 21 CFR §314.108(b)(5)(ii), the FDA may grant three years' further exclusivity for labeling changes made possible by clinical investigations. In December 2000, the FDA granted BMS that three-year extension with respect to pediatric indications for Glucophage. In devoting time and resources to its pediatric clinical trials on Glucophage, BMS therefore reasonably relied on its statutory right to six months' exclusivity for following the FDA's pediatric clinical study guidelines, and it right to additional exclusivity under Hatch-Waxman if its research culminated in FDA-approved labeling changes.

By undoing the benefits promised to BMS for completing clinical trials on Glucophage, the proposed legislation would be a breach of contract. As the Supreme Court recently held with respect to Congress's abortive bailout of the savings and loan industry, ''[w]hen the United States enters into contract relations, its rights and duties therein are governed generally by the law applicable to contracts between private individuals.'' United States v. Winstar Corp., 518 U.S. 839, 895 (1996) (plurality opinion). The Court affirmed

the core principle of Winstar last year in Mobil Oil Exploration & Producing S.E., Inc., v. United States, 530 U.S. 604 (2000). In that case, the Court was asked to analyze the validity of the Outer Continental Shelf Lands Act (''OCSLA''), which barred offshore drilling for which oil companies had previously paid the United States $158 million to receive permits. The court found that the passage of OCSLA violated the oil companies' rights under the contract, and that the government was required to return the $158 million. Id. at 624. This was the case, according to the Court, despite the fact that the permits the oil companies received only entitled them to pursue drilling if they subsequently fulfilled certain regulatory requirements. Id. at 621. As the Court found, ''[t]he oil companies gave the United States [a benefit] in return for a contractual promise to follow the terms of pre-existing statute and regulations. The new statute prevented the Government from keeping that promise. The breach substantially impaired the value of the contracts. And therefore the Government must give the companies their money back.'' Id. at 624 (internal citations and quotation marks omitted).

Just as was the case in the S & L and oil drilling situations, the proposed legislation here would deprive the party contracting with the government—in this case, BMS—the right to the benefit of the bargain it had struck with the United States. This breach by the government would entitle BMS to bring suit in the Court of Federal Claims under several theories of contract law, and would expose the United States to expensive and protracted litigation.

The SPEAKER pro tempore (Mr. FORBES). All time has expired.

The question is on the motion offered by the gentleman from Louisiana (Mr. TAUZIN) that the House suspend the rules and pass the bill, H.R. 2887, as amended.

The question was taken.

The SPEAKER pro tempore. In the opinion of the Chair, two-thirds of those present have voted in the affirmative.

Mr. BROWN of Ohio. Mr. Speaker, on that I demand the yeas and nays.

The yeas and nays were ordered.

The SPEAKER pro tempore. Pursuant to clause 8 of rule XX and the Chair's prior announcement, further proceedings on this motion will be postponed.

AMERICAN SPIRIT FRAUD PREVENTION ACT

Mr. TAUZIN. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 2985) to amend the Federal Trade Commission Act to increase civil penalties for violations involving certain proscribed acts or practices that exploit popular reaction to an emergency or major disaster declared by the President, and to authorize the Federal Trade Commission to seek civil penalties for such violations in actions brought under section 13 of that Act.

The Clerk read as follows:

H.R. 2985

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''American Spirit Fraud Prevention Act''.

SEC. 2. INCREASE IN PENALTIES FOR UNFAIR OR DECEPTIVE ACTS OR PRACTICES EXPLOITING REACTION TO CERTAIN EMERGENCIES AND MAJOR DISASTERS.

(a) VIOLATIONS OF PROHIBITION AGAINST UNFAIR OR DECEPTIVE ACTS OR PRACTICES.—Section 5(m)(1) of the Federal Trade Commission Act (15 U.S.C. 45(m)(1)) is amended by adding at the end the following:

''(D) In the case of a violation involving an unfair or deceptive act or practice in an emergency period or disaster period, the amount of the civil penalty under this paragraph shall be double the amount otherwise provided in this paragraph, if the act or practice exploits popular reaction to the national emergency, major disaster, or emergency that is the basis for such period.

''(E) In this paragraph—

''(i) the term 'emergency period' means the period that—

''(I) begins on the date the President declares a national emergency under the National Emergencies Act (50 U.S.C. 1601 et seq.); and

''(II) ends on the expiration of the 1-year period beginning on the date of the termination of the national emergency; and

''(ii) the term 'disaster period' means the 1-year period beginning on the date the President declares an emergency or major disaster under the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5121 et seq.).''.

(b) VIOLATIONS OF OTHER LAWS ENFORCED BY THE FEDERAL TRADE COMMISSION.—Section 13 of the Federal Trade Commission Act (15 U.S.C. 53) is amended by adding at the end the following:

''(e)(1) If a person, partnership, or corporation is found, in an action under subsection (b), to have committed a violation involving an unfair or deceptive act or practice in an emergency period or a disaster period, and if the act or practice exploits popular reaction to the national emergency, major disaster, or emergency that is the basis for such period, the court, after awarding equitable relief (if any) under any other authority of the court, shall hold the person, partnership, or corporation liable for a civil penalty of not more than $22,000 for each such violation.

''(2) In this subsection—

''(A) the term 'emergency period' means the period that—

''(i) begins on the date the President declares a national emergency under the National Emergencies Act (50 U.S.C. 1601 et seq.); and

''(ii) ends on the expiration of the 1-year period beginning on the date of the termination of the national emergency; and

''(B) the term 'disaster period' means the 1-year period beginning on the date the President declares an emergency or major disaster under the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5121 et seq.).''.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Louisiana (Mr. TAUZIN) and the gentleman from New York (Mr. TOWNS) each will control 20 minutes.

The Chair recognizes the gentleman from Louisiana (Mr. TAUZIN).

GENERAL LEAVE

Mr. TAUZIN. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days within which to revise and extend their remarks and include extraneous material on H.R. 2985.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Louisiana?

There was no objection.

Mr. TAUZIN. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, September 11 brought this country face-to-face with what was once thought to be an unimaginable series of events. However, these cowardly acts of terrorism sparked in this country an unprecedented level of generosity, an outpouring of spirit, of patriotism, but also of dollars.

Immediately, from every corner of this country, charities were inundated with money, with food, with clothing. Hospitals saw long lines of people offering to donate blood. Here in this Capitol complex Members and wives and husbands and staff lined up to donate blood. Shelters for the injured and homeless sprang up out of office buildings, restaurants and small businesses. Financial donations alone exceeded $1 billion.

If there is ever any silver lining in this national tragedy that this awful atrocity created upon the people of this land, it is this: We saw the incarnation of the American spirit again, the true strength of our country, the true, indeed, the blessed meaning of the United States of America.

But as with this and any disaster, there are unscrupulous people who will take advantage of that generosity. Unfortunately, this national emergency was no different. On the heels of the September 11 atrocities, we heard stories of scam telemarketers and scam charities trying to collect for ''disaster relief'' and crooks appearing to be affiliated with fire department fund-raising groups going door-to-door asking for funds. H.R. 2985 is aimed directly at these scam artists.

The American Spirit Fraud Prevention Act declares frauds during these times to be different. H.R. 2985 allows the Federal Trade Commission to increase civil penalties for unfair and deceptive acts or practices that exploit this Nation's reaction to a national emergency or a national disaster. With this bill, the FTC can collect up to $22,000 in civil penalties for each and every violation. This will send a strong and unequivocal message to criminals hoping to prey on the kindness of strangers, ''You will pay.''

I want to thank the gentleman from Georgia (Mr. DEAL) and the gentleman from New Hampshire (Mr. BASS), the original sponsors of the American Spirit Fraud Prevention Act. This is an excellent bill. I strongly urge its passage. I hope those who would scam the generosity of Americans in this tragic time will pay attention tonight, because, if they do not, the FTC will see you in court.

Mr. Speaker, I reserve the balance of my time.

Mr. TOWNS. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, as ranking member on this Subcommittee on Commerce, Trade and Consumer Protection, I am pleased to join the gentleman from